

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF SUFFOLK: PART 48

IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

August 18, 2020  
Central Islip, New York

MINUTES OF FRYE HEARING  
(Testimony of James Rafalski)

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Supreme Court Justice

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OFFICIAL COURT REPORTER

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2 THE COURT: Good morning. Please be  
3 seated everybody. We're waiting for some  
4 other people.

5 THE COURT OFFICER: Yeah. We're getting  
6 them in the hallway.

7 THE COURT: Good morning, Mr. Rafalski.

8 THE WITNESS: Good morning, your Honor.

9 THE CLERK: This is a continued hearing  
10 In Re Opioid Litigation, Index Number 400000  
11 of 2017.

12 Counsel, your appearance for the record.

13 MS. CONROY: Jayne Conroy, for  
14 Plaintiffs.

15 THE COURT: Good morning.

16 MS. CONROY: Good morning.

17 MR. BADALA: Good morning, your Honor.  
18 Salvatore Badala, for Plaintiffs.

19 THE COURT: Good morning.

20 MR. SHKOLNIK: Good morning, your Honor.  
21 Hunter Shkolnik, for Plaintiffs.

22 THE COURT: Mr. Shkolnik, good morning.

23 MR. SCHMIDT: Good morning, your Honor.  
24 Paul Schmidt, for McKesson.

25 MS. REISMAN: Good morning, your Honor.

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Sharyl Reisman, on behalf of Walmart.

THE COURT: Did you get that name,  
Stephanie?

COURT REPORTER: Yes.

MS. JONES: Good morning, your Honor.  
Stephanie Jones, on behalf of Walmart.

MR. O'CONNOR: Good morning, your Honor.  
Andrew O'Connor, on behalf of Mallinckrodt.

THE COURT: Good morning, Mr. O'Connor.

MR. O'CONNOR: Good morning.

THE COURT: Do you want to remind the  
witness?

THE CLERK: Mr. Rafalski, I'll remind  
you you're still under oath.

THE WITNESS: Yes. Thank you. I  
understand.

THE COURT: Mr. Schmidt, you may  
continue.

MR. SCHMIDT: Thank you, your Honor.  
May I just ask at the beginning if the sound  
is okay for the Court and the witness? I  
want to avoid any more indications of Led  
Zeppelin, if I humanly can.

THE WITNESS: Okay.

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THE COURT: Is there a question there?

THE COURT OFFICER: No. Just can you  
hear him okay.

THE COURT: You're fine.

MR. SCHMIDT: You can hear me okay,  
terrific. And you can hear me, Mr. Rafalski?

THE WITNESS: Yes, I can hear you.

BY MR. SCHMIDT:

Q. Okay. Yesterday we talked about how you  
got from the data you were given to your opinions  
for the New York pharmacies.

Today I want to talk about suspicious  
orders and about your flagging. Let me start  
generally with the obligation to report of  
suspicious orders. That applies to orders of  
unusual size, frequency or pattern, correct?

A Yes, sir.

Q. And that's contained in a regulation,  
right?

A Yes. That's, that's, that's not the  
only requirements, but those are guides contained  
within the registration. The registrant can  
certainly own a system that would -- that could be  
designed to have other identifiers.

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1 Q. And, sir, can I ask you to focus on my  
2 questions. There's a regulation that contains that  
3 requirement to report orders of unusual size,  
4 pattern or frequency, correct?  
5

6 A That is correct.

7 Q. You agree with me that that regulation  
8 gives some guidance on a suspicious order, but you  
9 think the actual full definition is up to the  
10 registrar depending on a lot of factors, the scope  
11 of their business, and the scope of those customers  
12 that receive products from them?

13 A Yes, sir.

14 Q. For example, the regulation does not  
15 tell distributors how to figure out if an order is  
16 of unusual size, correct?

17 A That's correct.

18 Q. That's up to the registrar to define,  
19 correct?

20 A Yes.

21 Q. There's no single generally accepted way  
22 to say this is an order of unusual size, correct?

23 A There's not any language specific to  
24 that statement, you mean, no, sir.

25 Q. There's no single generally accepted way

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to say this is an order of unusual frequency or unusual pattern, correct?

A That is correct, sir.

Q. And you're aware that government watchdogs, some of the ones we talked about yesterday, have recommended that it would be good for the DEA to develop additional guidance for distributors and manufacturers when it comes to suspicious order monitoring and suspicious order reporting?

A I am aware of that either publications or that information, yes, sir.

Q. And you agree with that recommendation, correct?

A Generally speaking, yes. Maybe not -- maybe you might interpret that question different than me, but, yes, generally, yes.

Q. Using your words in terms of lack of greater clarity from the DEA, the reason for the lack of greater clarity from the DEA is that you don't really think there's a one-size-fits-all suspicious monitoring system or program, correct?

A Yes. I don't think I used that exact terminology, but that concept would be consistent

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for the way that I answered about that, yes, sir.

Q. There's no one-size-fits-all suspicious order monitoring system, correct?

A Yes, that's correct. Yes, sir.

Q. Even today distributors or manufacturers are left to design their own suspicious order monitoring programs, correct?

A They are, yes, sir.

Q. And there's no generally accepted system saying this is exactly what a suspicious order monitoring system has to look like, correct?

A That's correct.

Q. As a result every distributor and every manufacturers' suspicious order monitoring programs are different from each other, right?

A Yes. Yes. In some ways there are some differences.

Q. And you read, as part of your preparation in this case, testimony from the DEA's former head of Office of Diversion Control, Joe Rannazzisi, correct?

A I have read some of his deposition testimony, yes, sir.

Q. I take it you saw that when he was asked



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about giving guidance or giving a checklist to registrants as to what's required to be in a suspicious order monitoring system, he said that's a business decision based on what the registrant's needs are, and the Drug Enforcement Administration does not tell a registrant what that specific system should look like.

Do you remember seeing that testimony from him?

A I do not recall that. I could review it, if you'd like, but I don't disagree with that statement.

Q. Well, that's where I was going. Maybe I can short circuit it.

Do you agree with the idea that when it comes to designing a suspicious order monitoring system, that's a business decision based on what the registrant's needs are, and the Drug Enforcement Administration does not tell a registrant what that specific system should look like?

A I agree with that statement.

Q. And I lost you for a second. Did you say you agree with that statement?

A I did. I agree with that statement,

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1  
2 sir.

3 Q. Evaluating suspicious order monitoring  
4 programs has to involve a company-by-company  
5 assessment, correct?

6 A You mean a customer-by-customer  
7 assessment?

8 Q. And companies-by-companies in terms of  
9 their business and who they're dealing with.

10 A Yes. Yes, sir.

11 Q. What works for one distributor or  
12 manufacturer in your view may not necessarily work  
13 for another, correct?

14 A It may work, but I don't think that I  
15 would impose one system from one company on another,  
16 but certainly there are some businesses that are  
17 very similar that potentially they could work.

18 Q. In your report you lay out some -- I  
19 think you call it key components that you believe  
20 should be included in a suspicious order monitoring  
21 system; are you aware of that?

22 A In my report?

23 Q. Yes, sir.

24 A I don't know if I say they should be  
25 included, if that's my exact language. I think that

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I might say that one would expect to see, but yes, sir.

Q. Well, actually, that's where I'm going.

Is it possible to have a compliant suspicious order monitoring system without all of those components?

A Depending on the scope of business or the type of customer, I think it's possible to not include some of those things.

Q. Okay. There are no -- stated differently -- there are no generally accepted set of requirements that every single suspicious order monitoring program must have, correct?

A Correct statement.

Q. Let's look at Plaintiff's Exhibit 1. Chris, it's Tab 1 in the binder that we -- it's Tab 1 in our document set that we used yesterday.

This is your report, Mr. Rafalski, and could we put that up on the screen, please. Page 45, please.

You have a section of your report that says, Analysis of the methodologies to quantify suspicious orders distributed in New York.

Do you see that?

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A Yes, sir.

Q. And if you look down near the bottom there, this refers to some analyses that are contained in Schedule 2 of your report, correct?

A Yes, sir.

Q. And just for ease of the record, I'd like to mark Schedule 2 as a standalone document. I think we're up to G, if I have my numbers right, G as in good. And could we pass out Tab 16 and put it up on the screen, please.

And what you see here, this is actually the conclusion of your report and the way you formatted it, it feeds straight into Schedule 2. And if we go through, just flip through the next series of pages, these are the calculations that you adopted from Dr. McCann, correct?

A Yes, sir.

Q. And they're all based on two appendices to the McCann report, Appendix 10 and Appendix 11, correct?

A Yes, sir.

Q. These are the only calculations or quantifications contained in your report relating to suspicious orders or flagged orders, correct?

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2 A Yes, sir.

3 Q. At your deposition, if we look at this  
4 exhibit, Schedule 2, there's a Methodology A  
5 starting at the bottom of page 1. If you go to page  
6 2, there's a methodology. You see the results of  
7 Methodology A, and then at the bottom there's  
8 Methodology B and so on with a total of five  
9 methodologies, correct?

10 A Yes, sir.

11 Q. In truth, you believe that only your  
12 first method, Method A, is plausible, correct?

13 A Well, I think they're all plausible.

14 Q. Okay. Let's take a look at Tab 2, your  
15 testimony from your deposition, February 7th 2020,  
16 page 198, lines 3 through 10.

17 And I'll omit the objection.

18 "QUESTION: Okay. Would any much of  
19 them be appropriate in your view for  
20 detecting suspicious orders? Would all five?  
21 Any of the five?

22 ANSWER: The first one is the only one  
23 that I think would be plausible."

24 Q. Did I read the question and your answer  
25 correctly?

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2 A Yes.

3 Q. Do you recall being asked that question  
4 and giving that answer under oath?

5 A Yes.

6 Q. And, in addition, you agree that you  
7 would not use the other four methodologies, other  
8 than Method A, correct?

9 A I don't think that was -- I don't think  
10 that was -- I think, I think I made statements in  
11 regards to the functioning of them and whether they  
12 would be -- so implausible and impossible, in using  
13 those words, there was one that I thought was a  
14 functioning formula.

15 The other ones I didn't think would,  
16 would accomplish or I wouldn't approve -- or I  
17 shouldn't say approve, that I don't think would  
18 function properly as a suspicious order system.

19 It -- but it wasn't about whether or not  
20 they could actually be applied, my understanding.

21 Q. My question is simply, you would not use  
22 the other four, correct?

23 A Well, it's not -- I did use them. It's  
24 not up to a question of use. It's just whether or  
25 not they could be properly functioning is what my

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2 question -- my responses to those deposition  
3 questions were my beliefs.

4 MR. SCHMIDT: Mr. Reynolds, can we go to  
5 the very next question and answer, lines 11  
6 through 13.

7 THE COURT: Go ahead.

8 BY MR. SCHMIDT:

9 Q. Do you see where you were asked in the  
10 very next question:

11 "Okay. You would not use the other  
12 four?

13 ANSWER: I would not."

14 Do you remember being asked that  
15 question and giving that answer under oath?

16 A Yes, sir. Again, I believe that was in  
17 regards to whether they should be used as a  
18 reasonable functioning suspicious order system.

19 Q. And in your view, Methods B through E  
20 should not be used as a reasonably functioning  
21 suspicious order system, correct?

22 A That would be my opinion and based on my  
23 experience in my previous investigations, that they  
24 would not function properly, that's correct.

25 Q. So why did you perform those? Why do

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those calculations appear in your report, sir?

A So at one point I was asked by the attorneys to provide some algorithms or diagnostic tools to apply to the transaction data. I elected to select four of them, which I reviewed as part of the investigation, that were used by the companies.

The other one I picked was the Masters' methodology or the Masters' diagnostic tool, and I picked that one because it was reviewed by the Appellate Court and -- reviewed by the Appellate Court. That was my purpose for picking that one.

Q. Masters being Method A?

A That's correct.

Q. Okay. Now, you just referred to being asked to perform additional methodologies by the lawyers, and that goes back to a point we addressed several times yesterday when I asked you why didn't you do this analysis, and you said the lawyers didn't ask me to.

Here you said you did this analysis because the lawyers asked you to.

What I would like to ask you is, is there any analysis contained in your opinions or your report or any opinion you reached without being



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asked to conduct that analysis or reach that opinion by the lawyers?

A Can you state it one more time, please.

Q. Of course. Yeah. I think the feed froze for a minute.

Is there any analysis that appears in your opinions or your report or any opinion you have offered that appears in your report that you were not asked to conduct or reach by the lawyers?

A No. If I understand the question, I think I was tasked to -- my opinion is based on the guidance or the framework of what my opinion is based on, and that was to -- the maintenance of effective controls, suspicious order system, and all of the things that encompassed the suspicious order system at the conclusion -- well, not the conclusion, but after my opinion was pretty much set by the review of all the documents and the records in regards to suspicious order systems and due diligence, then I was requested to provide these diagnostic tools and apply data.

I think it confirmed my opinions on the ineffectiveness of the suspicious order systems and the due diligence. Obviously, if they would have

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1  
2 been applied, it wouldn't have triggered any  
3 suspicious orders, then it would have definitely  
4 needed a review.

5 It's part of my opinion, but it's not  
6 the guiding post of my opinion. It's cumulative of  
7 everything, just like drawing back to my experience  
8 with the DEA.

9 Q. I'm going to try to simplify my  
10 question, because I think we're talking past each  
11 other.

12 Is there any analysis you've undertaken  
13 in your opinions or report that you were asked to  
14 undertake by the lawyers?

15 A No, sir.

16 Q. And is there any opinion you reached  
17 without specifically being asked by the lawyers to  
18 reach an opinion on that subject? Yes or no.

19 THE COURT: Just yes or no,

20 Mr. Rafalski.

21 A No. I'm just thinking about it. Sorry,  
22 your Honor. No, no, I don't think there is.

23 BY MR. SCHMIDT:

24 Q. Is there any -- and I'm going to flag  
25 this one for the Court and for Ms. Conroy because I

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1 don't think it runs afoul of the objection that was  
2 made yesterday, but I want to give that courtesy.  
3

4 Is there any analysis you did in your  
5 report entirely independently without taking  
6 something that was first prepared by someone like  
7 Dr. McCann or by lawyers and, in your words,  
8 adopting it as your own?

9 A This is my report, and these are my  
10 words. All of the information flowed through the  
11 attorneys. Some of it I found independent, but the  
12 critical information came from the attorneys, but it  
13 was my review and my evaluation of those documents.

14 Q. But in terms of the actual analysis, is  
15 there any of the analysis you did in the first  
16 instance yourself without someone else doing it  
17 first for you that you could --

18 A Sure. One example would be the review  
19 of due diligence records. That was my analysis,  
20 looking at the, the policies, the suspicious order  
21 systems that are formulas, the algorithms.

22 Many of the stuff I looked on my own.  
23 No one told me what the result -- what my opinion  
24 should be. It was my evaluation of that  
25 information.

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Q. And did you write that up in the first instance yourself, or did someone else write that up in the first instance for you?

A I think those were all my words and my writing, my drafts, those critical parts of the review.

Q. Okay. I want to go back to your methods. You talked a lot yesterday about what you did while you were at the DEA.

Am I correct that while you were at the DEA, the DEA never analyzed ARCOS data using the methodologies that Dr. McCann presented and you also presented in your report?

A That exact specific scenario, no, sir.

Q. You never used those methodologies, correct?

A No, sir.

Q. And I think the way I'm asking the question, I just want to make sure we're not talking past each other, what I said is correct, yes?

A I never specifically applied these methodologies during one of my occasions, and I'm not aware that the DEA did. I'm not saying they didn't, but typically these methodologies, no, sir.

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Q. Thank you. Before I dive into Methodology A, which is the one I'm going to focus on because it's the one that you rely on, I want to cover some general points about your work regarding flagged orders and suspicious orders.

And let's go back to Plaintiffs' Exhibit 1, your report, specifically the page we were looking at, page 45.

And if we call out the first paragraph under Heading 4, I want to focus on the language at the end of that first sentence.

I've described in this report the ways in which distributors and manufacturer Defendants inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids -- and this is the part I want to ask you about -- would potentially cause the diversion of these pills for nonmedical use.

Do you see that language?

A Yes, sir.

Q. Now, yesterday you went further, and if I heard you correctly, you said it's more likely than not that there was diversion, correct?

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A Yes, sir.

Q. That's not what you say in your report here. In your report you say it would potentially cause diversion of these pills, correct?

A I agree with what I say there, yes, sir.

Q. And I'd like to ask you about the gap between data you have, an analysis you did, and the opinion you seemed to give yesterday that it's more likely than not that there was diversion.

You did not review any of the individual orders reflected in this analysis, correct?

A That's correct.

Q. You did not perform an evaluation for any individual order to see if it was suspicious, true?

A That's a true statement.

Q. You were not offering any opinions on whether the orders flagged by your methodology are legitimate or suspicious?

A Can you repeat that, please.

Q. Yes, sir.

You do not intend to offer any opinions on whether the orders flagged by Dr. McCann, that you've adopted, are legitimate or suspicious?

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A And if we're speaking in regards to specific orders at this time, the answer would be that's correct.

Q. You did not review all the diligence files corresponding to triggered orders?

A That's correct. I did not review every diligence file.

Q. That's true for all distributors?

A Yes, sir.

Q. That's true for all manufacturers?

A Yes, sir.

Q. That's true for pharmacy Defendants in this case?

A Every specific due diligence file, that's a correct statement, yes, sir.

Q. You told us yesterday that it is absolutely important that there be an uninterrupted supply of prescription opioids for patients who need them; do you recall that testimony?

A I stand by that statement.

Q. You agree that manufacturers and distributors and pharmacies play an important role in ensuring an adequate and uninterrupted supply of legitimate prescription opioids, correct?

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A Yes, sir.

Q. And relevant to ensuring the distributors and pharmacies and manufacturers play that role, that critical role in ensuring an adequate and uninterrupted supply of legitimate prescription opioids, you don't have an estimate as to how much of prescribing or prescriptions are legitimate in terms of prescription opioids?

A I wasn't requested to conduct that analysis so, no, sir, I do not.

THE COURT: Mr. Schmidt, in connection with strictly a Frye analysis, strictly a Frye analysis, where are you going with this line of questioning?

Frye analysis over here, and, of course, examination during the trial of foundational material.

It seems to the Court, and perhaps it's far from me to question your needs and methods -- pardon the play on the words gentlemen and ladies -- what's the connection?

The Frye analysis -- the Court expects to hear a detailed explanation of



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methodology. The Court expects to hear testimony as to general acceptance or consensus of the methodology and testimony as to reliability.

It seems to the Court that a great deal of your examination is dealing with the application of the methodology and information by the witness. So if I'm mistaken, you'll tell me.

MR. SCHMIDT: Sure. I think it's directly relevant, and I'm guided by the Court's July 31st order on page 2 of the order quoting, I think it's the opinion -- quoting the commentary on Rule 7.01, and the Court states: The foundation is lacking if the trial court determines that there is simply too great an analytical gap between the data and the opinion offered, and it has a citation.

The question boils down to whether the expert's opinion sufficiently relates to existing data, or the contrary, is connected to existing data only by the ipse dixit, unproven word of the expert.

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THE COURT: Right. We're talking about what you read.

MR. SCHMIDT: Yes.

THE COURT: We're talking about trial, trial foundation.

MR. SCHMIDT: No, I think that's the Frye foundation. The Frye inquiry, as we understand it, as I think your Honor explained it in your July 31st opinion is methodology, part of methodology, part of general acceptance is how do they get from Point A data to Point B opinions.

And we had a very strong opinion given yesterday that didn't appear in the expert's report. I'm trying to show that there's no connection between what he did and how he got that opinion. That's core methodology. That's core general acceptance.

THE COURT: So what you're saying is there's a methodology, and your examination deals with the way, the means and methods of the witness in fulfilling that methodology, whatever that protocol is?

MR. SCHMIDT: Yes, sir.

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THE COURT: Okay. Go ahead.

MR. SCHMIDT: Thank you.

And I see why the last couple of questions triggered this, because they were more related to merits points, but I was trying to bring them back to the point that -- the last question I asked about, not assessing legitimate medical need.

BY MR. SCHMIDT:

Q. Mr. Rafalski, since you didn't look at any prescription data, when it comes to the percentages that you express in your Schedule 2, Court Exhibit G, you don't know what percentage of the orders you flagged went to fill legitimate prescriptions based on legitimate needs of patients, correct?

A That's correct, yes, sir.

Q. You don't know if any of the orders that you flagged in your methodology actually relate to any of the specific pharmacies you discuss in your report?

A Just so I can make a statement in there. I can't tell you --

Q. Move to strike.

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Sir, can you answer my question?

A Yes, but -- so you're -- so just so I'm clear, were actually diverted, my answer would be no, sir.

Q. No. And my question was, you can't tell me whether any of the orders you flagged in Schedule 2 related to any of the specific pharmacies you discuss in your report?

A No, sir.

Q. You can't tell me, just as you can't say how many went to legitimate medical prescriptions, you can't say how many of your flagged orders were actually diverted?

A So when you say "actually," I'm unable to tell you. I can't tell you exact -- actually what was diverted, but my opinion is is that it's more likely than not that, that there was diversion.

Q. How much?

A At least 51 percent. More likely than not.

Q. How much diversion, sir?

A I think I stated it's just more likely than not. I don't -- I can't give you an exact percentage.

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Q. I'm asking you a different question, sir. You identify a number of orders as flagged in your Schedule 2, correct?

A I do.

Q. How many of those orders were likely diverted, in your opinion?

A Well, my opinion is that there's not sufficient due diligence. It's more likely than not that all of them.

Q. If every single order you flagged were diverted, 51 percent likelihood; is that your testimony?

A Yes, more likely than not. If there's nothing to clarify whether or not that's a suspicious order, all the subsequent orders would be considered suspicious.

I think that's consistent with what Mr. Prevoznik's testimony in his deposition and even some internal documents or documents that I saw related to the companies.

Q. Okay. Stick with my question, because I think you're answering a question I didn't ask. Let's look at it concretely.

Can we put up Exhibit G, as in good, on

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2 the screen, Tab 16, and can we go to page 2, please.  
3 And let's just look at -- first of all, there's no  
4 New York calculations here, right, no New York  
5 State?

6 A That's correct.

7 Q. You don't know if the numbers were  
8 changed or would be the same, be higher, or be lower  
9 if you did all of New York State, correct?

10 A I was expecting to see a New York State,  
11 and when I wasn't provided that data, I didn't  
12 question it. I probably should have, and it wasn't  
13 placed in the report.

14 Q. And you don't know how different it  
15 would be?

16 A I do not.

17 Q. Let's look at what you do have.

18 At the top you've got Nassau County; do  
19 you see that?

20 A I do.

21 Q. And let's just pick a number from Nassau  
22 County. All right. I just want to look at  
23 something in my notes. Look, for example, at CVS  
24 hydrocodone. Do you see that?

25 A I do.

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Q. 88.9 percent?

A Yes, sir.

Q. Is it your opinion, more likely than not, that all 88.9 percent of those -- that all 88.9 percent of CVS's total oxycodone distributions in Nassau County were diverted? Is that your opinion? Yes or no.

A More likely than not, yes.

Q. Okay. So we've got close to 100 percent diversion from CVS in Nassau County; is that correct?

A That's correct.

Q. There is no -- there's only 10 percent legitimate medical use from CVS pharmacies in Nassau County, correct? That's your opinion? Yes or no.

A Yes, sir.

Q. And the same is true for -- if you go through every one of these calculations, almost, at least on your first page in your Method A, the lowest amount of legitimate medical use is less than 30 percent, correct? And I'm looking at Cardinal, oxycodone.

A That's correct.

Q. Have you ever seen, outside of you

1  
2 coming up with this number -- let me ask you this  
3 question.

4 Have you ever seen any DEA or any  
5 scientist or public health official try to estimate  
6 actual diversion using this method you've come up  
7 with?

8 A I think I've reviewed some when I was  
9 working with some materials that kind of explored  
10 the issue, but I've never seen any analysis or any  
11 studies that have come up with the actual amounts of  
12 diversion, that I'm aware of.

13 Q. Is there any general acceptance to using  
14 this methodology, not to try to flag orders, but to  
15 say what you just said, which is this is how much is  
16 actually diverted? Is there any general acceptance  
17 to that idea that you can point us to?

18 A Well, I wasn't the investigator on it.  
19 I think in general terms, yes.

20 Q. Okay. What general acceptance can you  
21 point us to where a human being, in the history of  
22 the DEA or the scientific community or the public  
23 health community, has ever used this Method A to  
24 estimate how much diversion is actually happening?

25 A Well, then I misunderstood your earlier



question --

Q. Let me re-ask the question then, and I didn't mean to cut you off.

A Well, yeah, but you did.

So the last question is, is -- was whether or not this type of analysis was used. I believe that it was in some cases.

Now, was it -- did they use specifically a, you know, methodology or diagnostic tool A, B, C or D, no, but within the DEA, I believe the same type of analysis was conducted to come to some conclusion on some of the cases, yes, sir.

Q. Okay. That's not my question, sir. Please focus on my question.

Can you point me to any time you're aware of when anyone has used Method A to try to estimate, not flagged orders, not even suspicious orders, but actually diverted orders; yes or no?

A No.

Q. Is it generally accepted? Is there any measure of general acceptance you can point me to for using Method A to estimate, not flagged orders, not suspicious orders, but actually diverted orders, as you have done in your testimony?

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2 A No.

3 Q. Are you aware that the DEA has actually  
4 used techniques to try to estimate the amount of  
5 diversion?

6 A Yes.

7 Q. And are you aware of the numbers that  
8 they have come up with when they use those  
9 techniques to estimate the actual rate of diversion?

10 A The actual numbers, no, sir.

11 Q. Are you aware that it's in the third  
12 decimal place .00X percent?

13 A No, sir.

14 Q. Would it help to see that?

15 A If you're asking me if I would see it,  
16 then I would answer yes, yes, but I'm not aware of  
17 it.

18 Q. Let's take a look at Tab 39.

19 Do you see that this is -- and let me  
20 give a second so the folks in the courtroom can get  
21 a copy. In the meantime, mark this as Exhibit H, H  
22 as in happy.

23 Do you see that this document, sir,  
24 comes from the Federal Register?

25 A I do, sir.

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Q. And you're familiar with publications.

If we look in the center, it's from the DEA,  
Department of Justice, Drug Enforcement  
Administration. You're familiar with publications  
they make in the Federal Register?

A Yes, sir, I am.

Q. Those are official statements of DEA for  
purposes of their operation; are you aware of that?

A Yes, sir.

Q. And if you look below, this official DEA  
statement relates to proposed aggregate production  
quota; do you see that?

A Yes, sir, I do.

Q. That's that quota we were talking about  
where DEA determines how many prescription opioids  
exist in the United States, right?

A Yeah. I believe it actually sets the  
overall amount of the controlled product utilized.  
I don't know if it gets as finite as your  
explanation, but generally, yes.

Q. And if you look at the date at the top,  
this is from September 12th. Please scroll up to  
the top, Chris.

A 2019.

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2 Q. Yeah. All right. Let's look at page 3  
3 of this document -- page 4. I'm sorry.

4 And do you see they have on the bottom  
5 left column, diversions estimates for 2018; do you  
6 see that?

7 A May I take one second to look at it,  
8 please.

9 Q. Of course.

10 A Can you scroll up to the top of the  
11 page.

12 MR. SCHMIDT: Chris, do you mind doing  
13 that.

14 THE WITNESS: Okay.

15 BY MR. SCHMIDT:

16 Q. So you understand that there was a law  
17 passed that required the DEA to estimate the amount  
18 of diversion, and that's what they're doing here,  
19 true?

20 A Yes, sir.

21 Q. And specifically, if we scroll back  
22 down, they're doing it for 2018?

23 A Yes, sir. I'm just looking because you  
24 quoted an actual percentage and I'm --

25 Q. You're not going to see it here.

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A Oh, okay, sir.

Q. It's slightly more complicated than that.

Do you see that for hydrocodone, it's 24.259 kilograms?

A Yes, sir.

Q. And if we look at oxycodone on the next page, it is 57.051; do you see that?

A Yes, sir.

MR. SCHMIDT: And, Chris, I don't know if there's a way we can kind of grab those numbers and keep them on the screen. I'm going to need to show the witness a second document. If there's not, I understand that.

BY MR. SCHMIDT:

Q. But you're aware that the DEA publishes on their website their actual quota year by year, right?

A Generally speaking, yes, sir.

MR. SCHMIDT: All right. If we -- Chris, look at Tab 40, please. If my colleagues in the courtroom could pass out Tab 40, which I'll mark as Exhibit I, and I'll ask if we could just blow up the title a

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little bit.

And I will represent to you we can go to the website and literally look at it, if you want, but this is from the Office of Diversion Control website.

If you click on quotas, there's another tab where you can click on and get the aggregate production quota history.

BY MR. SCHMIDT:

Q. Do you see that?

A Yes, sir.

Q. We can take that title down. If you look across the top, there's a year of -- there's a range of years. I'm going to focus on what DEA was focused on, 2018. Do you see that?

A Yes.

MR. SCHMIDT: And I'm sorry that this is not the most elegant way to be able to show this to you. It's hard doing this remotely, but, Chris, could we call out the line for hydrocodone sale and oxycodone sale, please.

BY MR. SCHMIDT:

Q. And I hope you can see this with me, Mr. Rafalski. I just want to lay out what the math

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is, and then I'll tell you what I get from these numbers.

The hydrocodone estimated diversion from the DEA is, if we look at the left, 24.259. Do you remember that number?

A Yes.

Q. And if we divide that by the 2018 number for total hydrocodone it's 43,027.640, correct?

A Yes, sir.

Q. And that comes up to .056 percent. Does that sound right to you?

A Yeah. I wouldn't argue with that. I'm not going to calculate it, but...

Q. And let's just do the same for oxycodone. It's kind of covered, if you can pull the left side down a little bit, Chris. There we go.

So for oxycodone the amount of diversion for 2008 is 57.051; do you see that?

A Yes, sir.

Q. Divided by 79,596.606. Do you see that?

A I don't see the .606. Is that the calculation you're doing?

Q. No. That's the number at the end of --

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THE COURT: It's a suggested calculation.

MR. SCHMIDT: No, it's actually not. That's the number reported in Exhibit I of the table. It's probably hard to read. Maybe we can blow up that number a little bit, the 79,596.606 under 2018, Chris.

BY MR. SCHMIDT:

Q. Do you see that?

A I can see that number, but my understanding is you're doing a calculation to come to a percentage of diversion.

Q. Yes, yes. So dividing the 57.051 by the 79,596.606.

A And the resulting number is?

Q. .072 percent.

A Okay. Did you -- I'm sorry. I'd like to write it down, because I'm thinking we may discuss it more, the hydrocodone number, the calculated number.

Q. And I'm rounding off what I understand generally accepted rounding principles. That's .056 percent, as I calculate it, and the oxycodone number is .072?



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A I think the thousandths is fine. Thank you.

Q. Okay. And my question is, in terms of the DEA's estimate of how much diversion is occurring, you recognize that as a generally accepted method of calculating the amount of diversion that has occurred?

A That's a very complex question. I understand the calculations you did, and I understand the data here. I mean, I don't, I don't know what the basis or how they came to the conclusion on the amount of diversion.

Obviously the DEA did it, my former agency, but I don't know what they used for the data to come up with that number. I accept that these are the numbers that were published, and I accept your mathematics.

Q. Do you have any different methodology for coming up with actual diversion than the numbers that the DEA has -- than the methodology that the DEA has employed here in this Federal Register publication?

A None, other than just looking at the potential volume that these numbers represent, and

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2 my experience working, and my knowledge of how the  
3 opioid epidemic is still, although not as bad, is  
4 continuing.

5 It would just be not a scientific study,  
6 but I think if I calculated out the dosage units, I  
7 probably would not agree with this calculation.

8 Q. Okay. You've not done that type of  
9 calculation of actual diversion that the DEA has  
10 conducted, correct?

11 A No, I have not.

12 Q. Okay. And you don't have alternative  
13 numbers using either their methodology or any other  
14 methodology for actual diversion for years, other  
15 than 2018, correct?

16 A I do not.

17 Q. Okay. Let me go back to some of the  
18 questions I was asking you.

19 Do you know if any of the orders that  
20 were flagged by Dr. McCann's methodology that you  
21 adopted, do you know if any of those orders were  
22 actually diverted?

23 A When you say the word "actually," I have  
24 to answer that no, sir.

25 Q. You don't know?

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A No, sir.

Q. To the contrary, would you agree with me that just a suspicious order in an amount outside of the normal, which is either an amount that's a large order, orders that are frequent orders, or the other criteria that's listed in the regulation, that in itself doesn't mean guarantee that it's going to be put into an illicit market?

Do you agree with that?

And I'll just ask, I don't know if you heard the end of what I said. Someone was not on mute, so I'll just ask that people on the phone be on mute.

Did you catch my question, Mr. Rafalski?

A Yeah, but if you would just ask -- I think it's a pretty critical question. Could you ask me it again, please.

Q. Yeah. Would you agree with the statement, in itself, just a suspicious order in an amount that's outside of the norm, which is either an amount that's a large order, orders that are frequent orders, or the other criteria that's listed in the regulation, that, in itself, doesn't mean guarantee that it's going to be put into an illicit

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2 market, there could be an explanation; do you agree  
3 with that?

4 A That's a pretty complex question. It  
5 has a lot of different areas.

6 No, I do not agree with that.

7 Q. Okay. Do you recall when you were  
8 working at the DEA, you were called on at various  
9 times to give testimony in cases?

10 A Yes, sir.

11 Q. Do you recall giving testimony in a case  
12 involving forfeiture relating to an entity HD Smith  
13 in 2011?

14 A Yes, sir.

15 MR. SCHMIDT: May I ask that Tab K2 be  
16 passed out and put up on the screen. We'll  
17 go ahead and mark this as Exhibit J. If we  
18 could put this up on the screen, please.

19 BY MR. SCHMIDT:

20 Q. Do you see that this is testimony,  
21 deposition testimony from you in a case called U.S.  
22 versus 463,497.72 in U.S. currency from Best Bank  
23 account dated May 17th 2011; do you see that?

24 A Yes, sir.

25 Q. And if we go to the next page, you see

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2 the formal caption, and a third of the way down it  
3 says, Deposition of James Rafalski.

4 Do you recognize this as your testimony  
5 in this case while you were an official at the Drug  
6 Enforcement Administration?

7 A I remember testifying in this matter,  
8 both here and at trial, yes, sir.

9 Q. Let's go to page 98 of your testimony,  
10 please, line 6 to 13. I'm just going to read the  
11 question and the answer.

12 "QUESTION: Okay.

13 ANSWER: --"

14 A Again, one second.

15 MR. SCHMIDT: Why don't we limit it just  
16 to the question and answer, Chris, and see if  
17 we can make it a little larger for the  
18 witness and for me, frankly. It's a curtesy  
19 for us older gentlemen.

20 It's line 6 through 13, please, page 98.

21 BY MR. SCHMIDT:

22 Q. Is that better, Mr. Rafalski? It is for  
23 me.

24 A Yes, sir.

25 Q. Okay. And I'll read starting at line 6:

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"QUESTION: Okay.

ANSWER: In itself, just a suspicious order in an amount that's outside of the norm, which is either an amount that's a large order, orders that are a frequent order, or the other criteria that's listed in the regulation, that in itself doesn't mean guarantee that it's going to be put into an illicit market. There could be an explanation."

Did I read that correctly?

A You did.

Q. Do you recall being asked that question and giving that answer while you were a government official in this case?

A Yes, sir.

Q. Were you being truthful in answering that question?

A I was.

Q. Do you agree that if you have a suspicious order -- I'm sorry. Do you agree that if you have a suspicious system in place and you get a large order for a specific product which generates a report, that doesn't automatically tell a

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distributor that they have to stop, cease shipping of all controlled substances?

A The complexity of that, so when an order is identified by the system, and it's identified as suspicious, until you dispel it, it's always going to be suspicious, and there's no way to know.

Now, if it's dispelled, there would be an explanation. That's the due diligence part. So that's what -- the complexity of your question, it's difficult to just say yes or no.

Q. Could we go to page 96, please, lines 12 through 20.

"QUESTION: Okay.

ANSWER: If you had information that a pharmacy or customers engaged in illegal conduct, you should stop all shipping, but if you have a suspicious system in place and you get a large order for a specific product which generates a report, that doesn't automatically tell a distributor that they have to stop, cease shipping of all controlled substances."

Did I read that correctly?

A Yes. And the key to that is to all

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2 controlled substances at the end.

3 Q. And do you recall being asked that  
4 question and giving that answer under oath as a  
5 government official?

6 A I don't have a specific recollection,  
7 but I'm not going to dispute the transcript.

8 Q. Okay. And you were being honest when  
9 you answered that question?

10 A Well, yes, sir.

11 Q. Okay. You don't know if any specific  
12 orders from the Defendants in this case caused harm  
13 to the public health; do you?

14 A In the case that we're reviewing here?

15 Q. Yes.

16 A Generally speaking, yes, I do.

17 Q. Okay. Let's go to your New York  
18 deposition, February 7th 2020, Tab 2, page 207. And  
19 let me just ask you one more time, sir, before we  
20 pull this up.

21 Do you know if any of these flagged  
22 orders actually caused harm to the public health;  
23 yes or no?

24 THE COURT: Page, line, question,  
25 answer. Thank you.



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MR. SCHMIDT: I was just giving him another chance before I went there, your Honor.

THE COURT: Page 207, line 11; is that what you're reading from?

MR. SCHMIDT: No. It's 7 to 10. Let's do the impeachment. Can we pull up 7 to 10, please.

MS. CONROY: I'm sorry, your Honor. Sorry to interrupt. Can I get this more clearly, the page and line number.

MR. SCHMIDT: Of course, Ms. Conroy.

MS. CONROY: Thank you. It's very difficult to tell just from the laptop.

MR. SCHMIDT: I apologize, Ms. Conroy.

It's the February 7th 2020 transcript, page 207, lines 7 through 10. And let me know when you're there and I'll continue.

MS. CONROY: I'm there. Thank you.

BY MR. SCHMIDT:

Q. Thank you.

"QUESTION: Okay. Do you know if any of these flagged orders actually caused harm to the public health?

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ANSWER: I do not."

Do you recall being asked that question and giving that answer?

A Not specifically, but I read it, and I don't dispute that that's what was asked and that's what I said.

Q. And you were trying to testify as truthfully as you could in giving the answer that, I do not know if these flagged orders actually caused harm to the public health, correct, at that time?

A Yes, sir. specifically to the word "actually," and I can't read the previous questions and questions subsequent to this, but the word "actually," the answer to that is I do not.

Q. Okay. So let me just see if I have that. You don't know if any of your flagged orders actually caused harm to the public health, correct?

A Actually, no. More likely than not, yes.

Q. Even though you performed these calculations -- well, I'll stand on that and leave it.

Even though you performed these calculations on the flagged orders, you don't have

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2 an opinion on how many should have been reported in  
3 New York, correct?

4 A On each specific order?

5 Q. For any of them. Let me ask the  
6 question differently.

7 Do you know how many should have been  
8 reported in New York?

9 A Specifically, no.

10 Q. You're not offering an opinion that any  
11 specific order from a manufacturer, distributor or a  
12 pharmacy should have been reported but was not  
13 reported, correct?

14 A I wasn't requested to do that analysis,  
15 so I don't have an opinion at this time, no, sir.

16 Q. And you are not suggesting in your  
17 report with this analysis that more orders should  
18 have been reported as suspicious; are you?

19 A I think that's what the report says.  
20 When there's the application of the methodologies,  
21 even the ones that, as you say, I wouldn't -- that I  
22 don't accept or wouldn't utilize, even those, those  
23 diagnostic tools, the three times multiplier still  
24 generate a significant amount of orders that should  
25 have been reported suspicious or were suspicious

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2 based on triggering the system and not having any  
3 due diligence conducted.

4 Q. You used the same methodology in the  
5 MDL, correct, the same Method A?

6 A Yes, sir.

7 Q. That Dr. McCann performed for you,  
8 right?

9 A Yes, sir.

10 Q. Let's look at your MDL transcript. This  
11 is May 13th 2019, Tab 17, at lines (sic) 179, 9  
12 through 25.

13 A Page, please.

14 MS. CONROY: Excuse me, your Honor.

15 Could I receive a copy of that transcript,  
16 please.

17 THE COURT: Yes, you can. Go ahead.

18 BY MR. SCHMIDT:

19 Q. Let me know when you have it, please,  
20 Ms. Conroy.

21 MS. REISMAN: Paul, can you repeat the  
22 tab number?

23 MR. SCHMIDT: Of course. 17.

24 Do you have it Ms. Conroy?

25 MS. CONROY: No, I don't. It looks like

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they're finding something, though.

MS. JONES: Is that the May 13th 2019 transcript?

MR. SCHMIDT: Yes, please.

MS. CONROY: I have it. Thank you.

MR. SCHMIDT: Thank you. And I'm on page 179, lines 9 through 25. Please tell me when you're there.

MS. CONROY: I'm there. Thank you.

BY MR. SCHMIDT:

Q. Okay. And I'll read the whole portion to you, but I'm going to focus on the first line of your answer.

"QUESTION: Are you suggesting in your report that more orders should have been reported as suspicious?

ANSWER: Well, I don't think it suggests that. I'll restate it again.

So when the system triggers a suspicious order, it doesn't reset to the next order to be a suspicious order. So how I interpret the regulations and how my training is and how the Masters ruling and some of the documents I've read in regards from McKesson

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and Cardinal and Prevoznik's deposition testimony, is that once a suspicious order is identified by registrant, it should be stopped and there should be a due diligence to dispel whether or not that suspicious order is, in fact, suspicious."

Do you recall being asked that question and giving that answer about your Method A?

A Yes, sir.

MS. CONROY: Your Honor, the entire answer was not read.

THE COURT: Read the entire answer, Mr. Schmidt, please.

MR. SCHMIDT: Can you scroll down. I thought I did read the entire answer. I apologize for that.

Oh, you're right. I apologize.

BY MR. SCHMIDT:

Q. "If the registrant takes no action and just continues to ship subsequent orders in that order, then they're all suspicious orders.

Now, my last paragraph kind of sums up that this is how I applied this, and, you know, it's in regards to how the Court would or would not

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2 accept it, and there would be other methodologies.  
3 So that's how I interpret it."

4 Did I read that correctly?

5 A Yes, sir.

6 Q. Do you recall being asked that question  
7 and giving that answer?

8 A Yes, I do.

9 Q. You don't know if the DEA or the State  
10 of New York would have taken action on any of these  
11 flagged orders if they were reported, true?

12 A I have no way to know that, no, sir.

13 Q. And as to orders that were reported, are  
14 you aware that there were well over 10,000  
15 suspicious orders reported just by McKesson,  
16 Cardinal and ABDC in the State of New York?

17 A Not that specific number. If you wanted  
18 to show me some documents for, you know, to confirm  
19 those specific numbers. I know there were reports,  
20 but off the top of my head, I don't know it was  
21 10,000.

22 Q. Are you familiar with the Plaintiffs'  
23 expert named Lacey Keller?

24 A The name, yes, sir.

25 Q. Have you reviewed her materials and her

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estimates of the over 10,000 suspicious order reports that Cardinal, ABDC, McKesson made in the State of New York?

A I have not.

Q. Okay. As to whatever volume of suspicious orders the Defendants in this case made to the State of New York, you don't know what percentage of the actual suspicious orders that were made were actually acted on by New York, correct, or the DEA?

A No, sir. You started to interrupt. Sometimes I think you're done when you ask the question, and then you add a little bit.

Q. You're doing fine, sir. That's a terrible practice I have. My brain works slowly.

In fact, you're not aware of any suspicious order reports regarding pharmacies that led to an investigation, correct?

A Can you ask it again and maybe just a little slower, please.

Q. Yes. You're not aware of any suspicious order reports regarding pharmacies that led to an investigation?

A That's correct, I am not.



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1 Q. Let's go back to your Schedule 2, to  
2 your report, and can we put that back up on the  
3 screen. As you can probably see, I'm having trouble  
4 finding my copy of it.  
5

6 Here it is. It's Exhibit G, please.  
7 And look at the first page. You indicate on the  
8 first page -- could we put that up, Chris, Exhibit  
9 G.

10 You indicate on the first page that your  
11 analysis runs from 1996 to 2018; do you see that?

12 A Yeah. Those numbers are incorrect.

13 Q. Instead of doing it for that 22-year  
14 period, you only did it for the nine-year period of  
15 2006 to 2014, correct?

16 A That's correct.

17 Q. You actually believe the opioid crisis  
18 goes back to before 1999, right?

19 A I don't think I testified to that. I  
20 think that's close to the onset of the internet  
21 pharmacies and the OxyContin.

22 I think my prior testimony would say it  
23 would be around the 1999 time period.

24 Q. Okay. You don't know how your numbers  
25 would change if you used the full period you talk

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2 about here in terms of evaluating flagged orders,  
3 correct?

4 A If I amended the timeframe?

5 Q. Yes.

6 A Since I didn't do those calculations, I  
7 don't want to provide any opinions.

8 Q. Let's go to page 2, please.

9 You did not perform the math in these  
10 calculations; that was done by Dr. McCann, right?

11 A It was.

12 Q. You've never talked to Dr. McCann?

13 A I've talked to him, yes, sir.

14 Q. You didn't talk to him at the time that  
15 you turned in this report; did you?

16 A Well, your first question was pretty  
17 broad. Specifically about this report, no, sir.

18 Q. You didn't read his deposition in the  
19 New York case; did you?

20 A I read portions of it.

21 Q. But not in its entirety?

22 A No, not the entirety.

23 Q. You've not checked his calculations;  
24 have you?

25 A Definitely I have not done that, sir.

1 Q. And in terms of what we see on this  
2 page, your Method A, this is, again, copied in this  
3 case word for word and number for number from what  
4 Dr. McCann did, correct?  
5

6 A That would be my expectations, yes, sir.

7 Q. You didn't change anything?

8 A I did not.

9 Q. And even the format that this appears  
10 in, that was given to you and adopted by you as your  
11 own, in your words, correct?

12 A The Excel spreadsheet system, yes, I  
13 didn't design this. That's correct.

14 Q. You didn't know, until we talked at your  
15 deposition, that in coming up with these numbers and  
16 getting from the data to the opinions you offered,  
17 the methodology he used, that you adopted, you  
18 didn't know until we talked at your deposition that  
19 he had to make some judgment calls in coming up with  
20 these numbers; did you?

21 A So I remember that testimony, and I  
22 think there were some -- I think the term that was  
23 used was assumptions, and I was a little confused by  
24 that.

25 I know there was some questions on how

1  
2 to apply the methodology, and I -- so I may have  
3 answered that I did not know, but I think I was  
4 confused by the question.

5 Q. You knew his algorithm required certain  
6 judgment calls?

7 A Well, I had some discussions or -- not  
8 directly with him in regards to the start and stop  
9 point, whether it was 30 days or whether it was  
10 calendar months, but specifically I know there was a  
11 little bit of he needed to make some assumptions or  
12 judgments to run it, but specifically, I didn't have  
13 any conversations directly with him about it.

14 Q. And you can't say, one way or another,  
15 whether you agree with the judgment calls he made in  
16 performing his algorithm, correct?

17 A That's not a totally true statement. So  
18 on applying the Methodology A, if you went by the  
19 calendar months, I would agree. I agree with that.

20 Q. Is it true that you don't know the  
21 entirety of his judgment calls?

22 A I reviewed his deposition testimony. If  
23 there's some outside of that, I would not be aware  
24 of them.

25 Q. Okay. Let's look at your February 7th

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2 2020 deposition transcript, page 204, line 13 to 22.

3 This is Tab 2, page 204, 13 to 22.

4 "QUESTION: Okay. Maybe that answers my  
5 next question, which is do you know, can you  
6 say one way or the other whether you agree  
7 with the judgment calls he made in performing  
8 his algorithm?

9 ANSWER: I don't know the entirety of  
10 his judgment call, so I can't, I can't answer  
11 that question."

12 Did I read that correctly?

13 A You did.

14 Q. Do you recall being asked that question  
15 and giving that answer at your deposition?

16 A I don't specifically recall it, but I  
17 don't dispute the deposition record.

18 Q. Do you dispute the truth of that  
19 statement?

20 A Yes, sir.

21 Q. You do dispute the truth of that  
22 statement that you made?

23 A I do not. I'm sorry.

24 Q. Okay. And you looked at his testimony.  
25 Do you see the part of his testimony where he said,

1 I probably would come up with 5 or 10 different  
2 small decisions that needed to be made in order to  
3 operationalize it? Did you see that portion of his  
4 testimony?

5 A I don't specifically recall that.

6 Q. Okay. Do you know what the 5 to 10  
7 decisions he had to make to be able to perform his  
8 Method A calculation that you relied on? Do you  
9 know what those 5 to 10 decisions were?

10 A No, sir.

11 Q. So not knowing how he took the data and  
12 made the 5 to 10 decisions, you don't know how far  
13 of a gap there is between his outputs and that  
14 additional data in terms of those 5 to 10 decisions  
15 that he made; am I correct in that?

16 A Yes, sir. That's correct. That is a  
17 correct statement.

18 Q. Now, let's show the Judge how your  
19 method works in application.

20 Under your Method A, you look to see if  
21 the level of opioids in a given month is more than  
22 any in the prior single six months, right?

23 A Trailing six months, yes, sir.

24 MR. SCHMIDT: And if we illustrate that,  
25

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can we pull out Demonstrative Exhibit 4?

We'll mark this as Court Exhibit K. Let me just give a moment for it to be passed out in court.

BY MR. SCHMIDT:

Q. So do you see I've written up on the screen, Year 1. I start in February, 5,000, go through July, and the number of pills vary per month, 5,000, 10,000, 7,000, 8,000, 9,500; do you see that?

A I do.

Q. And do you recognize that these are the very same numbers that Dr. McCann gives as an example in his report?

A Yeah, I believe he does, yes, sir.

Q. Right. So under your methodology, if we go to page 2 and assume that in August their 10,000 pills, that would not be suspicious because it's not higher than March, which is the highest of the prior six months; is that how your methodology works?

A Yes, sir.

Q. Let's go to page 3, and we'll mark that green, just to show that it's not suspicious; fair?

A Yes, sir.

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MR. SCHMIDT: Okay. Let's do another assumption, and I'll do this side by side, if we can go to page 4. If instead, and I think we got the wrong one loaded, Chris. Could someone on the line tell me the right one to ask for, because I think it should be 10,100.

Chris, if we could use the file that has yesterday's date in the title. Bear with me. We changed it here in your testimony yesterday to try to make it consistent with your testimony, Mr. Rafalski.

THE WITNESS: I understand.

BY MR. SCHMIDT:

Q. There was one point, you'll remember, where the Judge asked you if you had one pill extra, does that trigger your suspicious order. You said, Well, you know, you don't really see one pill. You might see one bottle, which is 100 pills.

Do you remember saying that?

A I do.

Q. Okay. And so that's --

A They don't sell the pills one pill at a time, so that's why I made that statement, sir.

Q. Understood, understood. And that's why



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we changed this overnight.

So you'll see page -- I'm going to mark this one as Demonstrative Exhibit 10. I think your Honor and Ms. Conroy, this is the version that was given out in court.

You'll see page -- let's go back to page 1, that's the assumption. Page 2, that's if you have 10,000. Page 3, that's based on suspicious. And now let's go to where we were on page 4.

If instead of having 10,000 pills in August, you have 10,100, you have one bottle extra; do you see the difference between these two?

A I do.

Q. In that scenario, that would be suspicious under your methodology, correct?

A Not my methodology.

Q. Sir, I will withdraw my question and rephrase it.

Under Method A, that 10,100 would be flagged, correct?

A The diagnostic tool or the suspicious order system would have flagged that order, yes, sir.

Q. And let's go to the next one and mark it

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red so we can see the difference between what gets flagged and what doesn't get flagged.

Do you know of any generally accepted suspicious order methodology that identifies an order as suspicious based on the amount of a single pill bottle in one month?

A I think if there's an established threshold for any suspicious order system, my answer to that would be yes. Anything that would exceed the threshold would be triggered as a suspicious order.

I can see that, that this hypothetical example of 100 pills, I can see that probably the DEA wouldn't rush into action for a 100-pill bottle, but that's the integrity of the system. The person who designs -- the company that designs the system designs it, a trigger.

So the 100 is the trigger. The resolution of a 100-pill bottle would probably be an easy resolution, an easy due diligence. Hypothetically, that August number could be 30,000. So -- but the answer is yes, the system would stop that order and it should.

Q. Would it automatically report it

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1  
2 regardless of what that, what the company finds  
3 looking at that order?

4 A The system would report it. No, sir.  
5 That's up to the registrant.

6 Q. Okay. Now, your methodology, the six  
7 months does not build in slight increases from month  
8 to month in the threshold to account for the fact  
9 that there are time periods in which prescribing  
10 levels were increasing, correct?

11 A Again, I don't want to correct you.  
12 This isn't my methodology. This was the methodology  
13 that was used by Masters, and they elected not to  
14 build that component into this system.

15 I just used the system as it was  
16 designed.

17 Q. Sir, this methodology, Methodology A  
18 does not build in slight increases from month to  
19 month to account for time periods in which doctors  
20 were making the medical judgment to prescribe more  
21 opioids, right?

22 A It does not build that in, that's  
23 correct.

24 Q. It doesn't adjust threshold levels at  
25 all based on whether doctors are making the judgment

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to prescribe more legitimate prescription opioids or less, correct?

A There's no components for doctors. It's up to the company that designed it to make the decision on whether or not to ship increasing amounts of that drug.

Q. Should a suspicious order monitoring program take into account changes in medical practices, such as whether doctors were prescribing more or fewer prescription opioids? Yes or no.

A There's not a yes-or-no answer to that because of the qualifications.

Q. Okay. Do you know of any generally accepted methodology for detecting suspicious orders and reporting them that ignores legitimate medical practices and legitimate medical trends in prescribing? Do you know of any such methodology?

A That's another qualified question that's not a simple yes-or-no answer.

Q. Okay. And let me just phrase it differently, and then I'll move on. Can you point me to any generally accepted methodology for identifying and reporting suspicious orders that ignores entirely what the medical community is doing

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in terms of whether they're making the judgment to prescribe more for legitimate reasons or less for legitimate reasons? Can you point me to any such methodology? Yes or no.

A Specific methodology, the answer would be no.

Q. Let's talk about the second part of your calculation.

Once an order gets flagged like this 10,100, every order from that pharmacy after is flagged, correct?

A Well, that's the assumption I made based on my review. That's not -- if you're asking if a suspicious order system just in itself, that was a general question.

Could you state that one more time, please.

Q. Yes. Under this method that you're using, once an order is initially flagged, every order after that gets flagged, too, correct?

A Only if the suspicion is not dispelled through a due diligence or a review by the company. If they just ship this amount and continue you on without dispelling it, my answer is yes.

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Q. If there was an additional flagged order that was flagged as suspicious, you treated every subsequent order as suspicious, correct?

A Based on my review of the documents, the totality of circumstances, that assumption was yes.

Q. Okay. And --

A Based on the fact that it was just triggered as 100 pills over, still on that example, there's other circumstances that was drawn with my opinion.

Q. Okay. I don't think you're answering my question, so I'm going to try to make it as simple as possible. Just answer it yes or no.

If there was an initial flagged order that was flagged as suspicious, you treated every subsequent order as suspicious, correct? Yes or no.

A Yes.

Q. Thank you.

And you did that on the assumption that there was no further diligence? Yes or no.

A No. There was insignificant or insufficient -- I'm sorry -- due diligence, and it was not -- it was not just specific to that order. It was based on a totality of circumstances.

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1 Q. But in terms of the gap, the  
2 methodological gap between the data you had and the  
3 opinion you reached, the assumptions you used, you  
4 didn't look at all the due diligence files to see if  
5 it was correct for every one of these orders, there  
6 was, in fact, insufficient diligence, true?

8 You didn't review those diligence files?

9 A If I understand your question, if you're  
10 asking order by order, the answer would be I did  
11 not.

12 Q. Okay. Let's go back to Demonstrative 4,  
13 just to illustrate how this method works. I'm going  
14 to take that second example where you have the one  
15 extra pill bottle and that triggers it as flagged.  
16 And I'm going to telegraph that out over eight  
17 years, which is the time period you looked at.

18 Can we go to the next page, please. And what  
19 you will see is I've repeated the pattern from the  
20 first six months to 5,000, 10,000, 7,000, 8,000,  
21 9,000, 9,500, again and again and again so that no  
22 subsequent month exceeds those first six months,  
23 only the 10,100 in August does.

24 And if you go to the next page, you'll  
25 see it continues out eight years.

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Do you see that, Mr. Rafalski?

A I see your, your numbers, yes, sir.

Q. If you go back to the prior page, under your methodology, that one bottle in that one month triggers every subsequent order as suspicious; true or false?

A Under this hypothetical situation and those numbers, I would say that statement is true.

Q. Have you ever heard of the DEA acting against a company, yes or no, based on one bottle going over the threshold in one month? Yes or no.

A No.

Q. I want to go back to -- and this will lead into my final topic, Mr. Rafalski.

I want to go back to, do you remember those PowerPoints that Ms. Conroy walked through with you?

A I do.

MR. SCHMIDT: I want to go back to that PowerPoint.

Are you able to pull that up, Chris.

And let's go to slide 7, please. This is where you talk about maintenance of effective controls.



BY MR. SCHMIDT:

Q. Do you see that?

A Yes, sir.

Q. And I want to see if I understand some elements of this. Let's go first to the second bullet. Do you see the second bullet? It says, Thresholds.

A Yes, sir.

Q. You agree with me that you can have an adequate suspicious order monitoring system without having thresholds, correct? They're not required?

A If your question is, are they specifically stated in the regulation, my answer is I agree with that.

Q. Let's go to bullet 5. Due diligence must be robust, well documented and retained.

Do you see that?

A Yes, sir.

Q. We have the benefit of federal regulations that actually say very specifically certain types of documents need to be retained by companies, correct?

A If you're speaking to the Code of Federal Regulations, there are specific documents

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that have a retention that requires a retention period.

Q. And there's nothing in the Code of Federal Regulations that specifically says diligence files have to be maintained, true?

A Nothing in the Code of Federal Regulations specifically speaks to due diligence, I agree.

Q. Are you aware of DEA ever taking action against a distributor solely because they didn't retain diligence files? Yes or no.

A No.

Q. Did you ever take action against a registrant solely because they did not retain due diligence files when you were at DEA?

A Well, that's a different question. You said specifically -- your first question was narrow. Just because they didn't retain maintenance of effective -- I mean, due diligence files, I think -- can I finish, please?

In that question, I want to restate that. I think I'm not going to answer that, because I'm sure that it's more likely than not that some office maybe did their call letter of admonition and

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some letter that would have guided a company.

It's a low level of punitive nature. I don't have any knowledge personally of that occurring, but I think it's more likely than not there might have been some action over this entire time period.

Your second question, certainly my Masters case was a result of the due diligence in that action, but it was encompassing many things, not specific, but that was one of the core things was the maintenance of records and the type of due diligence. So I would answer yes to the second question.

Q. Do you remember what the second question was?

A Yes. Whether the DEA ever took actions by using -- in regards to due diligence files, I think it was a more general question, and it would be part of, not specifically, but I think it broadened -- that second question broadened it.

Q. No. Let me re-ask my two questions.

Do you have any facts you can point us to, any facts, any evidence you can point us to to say the DEA took action at any point in time in the

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history of the DEA against a registrant, a distributor, manufacturer or pharmacy solely because of their failure to maintain diligence files? Yes or no.

A No.

Q. Can you point me to any time you, while you were at DEA, ever took action against a registrant solely because of their failure to maintain due diligence files? Yes or no.

A Let me think a second about that, please.

I don't have any recollection at this time, so I would say no.

Q. Okay. Now, let me go to one more of these requirements that you list.

Let's look at the fourth one. Conduct due diligence of orders flagged as suspicious. And you say, Only when such orders have been cleared of suspicion can they be shipped. Do you see that?

A Yes, sir.

Q. And that, in kind of industry jargon, refers to something called the do-not-ship requirement, correct?

A Yes, sir.

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Q. The blocking requirement, correct?

A Yes, sir.

Q. Do you understand the DEA has only directed distributors not to ship until they clear the suspicious orders since 2006?

A No. I think there's guidance way back into the 1980s in regards to that.

Q. Okay. Let's talk about that, and that will be my last topic.

THE COURT: We're not talking about the 1980s. Mr. Schmidt, start to wrap it up. You asked for an hour yesterday. You're about an hour and-a-half now.

Despite your comments about this Court's Short Form Order, you're going far afield. Start wrapping it up, sir.

BY MR. SCHMIDT:

Q. Okay. Did you give testimony when you were at the DEA in that Court decision we looked at where you stated your views as a United States official that until 2006 registrants were told -- were not told to block orders that they flagged as suspicious? Did you give such testimony?

A Without seeing the testimony, I think

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1  
2 it's possible at that time I wasn't aware of all  
3 these documents that I've since learned about in  
4 doing, in part as being asked to give an opinion in  
5 this litigation, but it's possible I did say that.

6 Q. Do you remember me showing you that  
7 testimony at your deposition and saying you recall  
8 giving it?

9 A I have a recollection of the discussion,  
10 but specifically I'd like you to show it to me, but  
11 I don't -- you know, I think that there's a  
12 possibility that that did occur.

13 MR. SCHMIDT: Your Honor, I'm happy to  
14 show it to him. I'm trying to be mindful of  
15 your Honor's admonition to wrap it up. I can  
16 wrap it up or I can show it to him, as your  
17 Honor directs.

18 THE COURT: I missed the end of it.

19 MR. SCHMIDT: I'm sorry, your Honor. He  
20 just asked to see the testimony. I'm happy  
21 to show it to him, but I also want to be  
22 mindful about what your Honor said about  
23 coming to a conclusion.

24 Can I show him the testimony and then  
25 finish, or should I just finish?

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THE COURT: What do you want to show him?

MR. SCHMIDT: It's the same testimony that you were looking at previously, Exhibit A.

THE COURT: Is this the last thing you're going to show him?

MR. SCHMIDT: Yes, sir.

THE COURT: Go ahead.

MR. SCHMIDT: Thank you, your Honor.

BY MR. SCHMIDT:

Q. Do you remember this testimony from the case where you were the lead investigator?

A We're talking at deposition or at the trial?

Q. At the deposition.

A I remember giving testimony for a deposition, yes, sir.

Q. Let's look at page 89 -- I'm sorry -- I think I'm actually talking about the trial testimony. Hold on. Yeah, it's this testimony. Let's look at page 89.

MS. CONROY: So, I'm sorry, Mr. Schmidt.

I'm to look at the deposition testimony or

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2 you'll give me the trial testimony?

3 MR. SCHMIDT: It's the deposition  
4 testimony, Ms. Conroy.

5 MS. CONROY: Thank you.

6 MR. SCHMIDT: Of course.

7 Look with me at page 89, line 22.  
8 Chris, this is Tab 22, Exhibit J, page 89,  
9 start with line 22, and then we're going to  
10 continue on to page 90.

11 THE COURT: Mr. Rafalski, is this a  
12 forfeiture proceeding?

13 THE WITNESS: Yes, sir. It was a civil  
14 trial --

15 THE COURT: You answered my question.  
16 You answered my question.

17 THE WITNESS: -- in regards to -- yes,  
18 sir.

19 MR. SCHMIDT: And let's start with 89,  
20 line 22, through page 90, line 13.

21 THE COURT: Question, answer, question,  
22 answer.

23 MR. SCHMIDT: "QUESTION: Is it your  
24 understanding of the requirement that a  
25 distributor is not to ship any suspicious



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2 orders?"

3 And then I'm going to skip over the  
4 lawyer objections. Let's go to page 90 down  
5 to line 13.

6 "THE WITNESS: If a firm identifies as a  
7 suspicious order, they are not supposed to  
8 ship it.

9 QUESTION: Any suspicious order, that's  
10 your understanding?

11 ANSWER: Yes.

12 QUESTION: And where is it contained in  
13 regulations or the statutes that you cited?

14 ANSWER: It's not contained in those  
15 regulations and statutes, but it's been --  
16 they've been informed of that policy by the  
17 DEA.

18 QUESTION: Okay.

19 ANSWER: And these distributors."

20 Did I read those questions and answers  
21 correctly?

22 A I don't dispute those statements.

23 Q. And then the other quote that tells us  
24 when that occurred is page 91, line 17 through 22.  
25 You can probably just do line 20 through 22. 91,

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line 20 through 22.

"QUESTION: When was that briefing?

ANSWER: The first briefing was in 2006,  
I think January 2006."

Do you see that? Did I read that  
question correctly, and do you recall giving that  
answer?

A I don't recall specifically, but I don't  
argue with the record.

Q. If you said earlier you've come to learn  
that there was actually contrary guidance, that's  
only since you've been hired as an expert in this  
litigation, correct?

A That's correct.

MR. SCHMIDT: Thank you, Mr. Rafalski.  
That's all I have.

THE COURT: Mr. O'Connor?

THE WITNESS: Thanks for the  
forbearance, your Honor.

THE COURT: Mr. O'Connor, are you with  
us?

MR. O'CONNOR: Yes, your Honor, I'm  
here. If I can suggest that we take a short  
break now, I'll confer with my manufacturer

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2 colleagues, and I may be able to streamline  
3 this.

4 THE COURT: Okay. We'll take ten  
5 minutes. Thank you very much.

6 Mr. Schmidt covered a great deal of  
7 territory.

8 MR. O'CONNOR: I understand.

9 THE COURT: Thank you. Ten minutes.

10 (WHEREUPON, a short recess was taken.)

11 THE CLERK: Remain seated, come to  
12 order.

13 THE COURT: All present and accounted  
14 for. I have to look at something. Hang on.

15 This is for everybody's information.

16 On July 8th of this year in a case  
17 called Guerra, G-U-E-R-R-A, versus Ditta,  
18 D-I-T-T-A, July 8, Second Department, Slip  
19 Opinion 03771, the Appellate Division made it  
20 abundantly clear -- who's that? Hello? All  
21 right -- separate and distinct from the Frye  
22 inquiry is the admissibility question --  
23 who's doing that? Are you picking that up?  
24 Any idea?

25 MS. LICARDI: I just muted them.

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THE COURT: I'll start again.

Separate and distinct from the Frye inquiry is the admissibility question applied to all evidence at trial. Let me say it again. At trial. Hyphen, whether a proper foundation to determine whether the accepted methods were properly employed in a particular case.

All right. So at trial accepted measures were properly employed, all right. The purpose -- by the way, this is not from the case. This is other cases.

The purpose of a Frye hearing is to determine whether proposed expert testimony about scientific techniques were properly performed to generate results that generally are accepted as reliable within the scientific community.

That was later extended a bit with use of the word consensus. Consensus was a word used by Justice Kaye. I believe it's a concurring opinion in the Mobil Oil case.

So going forward, I expect everybody, Plaintiffs and Defendants, to be mindful of

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what the purpose of a Frye hearing is, and rather than choose to cross-examine an expert or examine an expert based upon the A, B, C, Ds and Es through X, Y and Zs of their testimony, should they testify at trial, refrain, because if counsel doesn't raise the objection, the Court will, okay?

Mr. O'Connor, go ahead.

MR. O'CONNOR: Thank you, your Honor. After conferring with the other manufacturers, I'm happy to report we can streamline things here by asking the witness to the pharmacies no questions.

THE COURT: Ms. Conroy? Mr. O'Connor, thank you.

MS. REISMAN: Your Honor, your Honor?

THE COURT: I'm sorry. You indicated you may have a few questions.

MS. REISMAN: Your Honor, I have literally a handful of questions.

THE COURT: A handful is five.

MS. REISMAN: And I probably won't go over that. Your Honor, may I approach without a mask?

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THE COURT: Yes.

Do you know what the hardest three words are in a trial lawyer's vocabulary?

MS. REISMAN: What are they, your Honor?

THE COURT: No further questions.

MS. REISMAN: Fair enough, your Honor. Good morning, your Honor.

THE COURT: We have your appearance, of course, right?

MS. REISMAN: Yes. Sharyl Reisman on behalf of Walmart.

CROSS-EXAMINATION

BY MS. REISMAN:

Q. Good morning, Mr. Rafalski. How are you?

A Very good. Thank you. Good morning.

Q. We've not had the opportunity to meet before, and this will be very brief. I just have a few questions for you about the performance of your methodology in this case to confirm what I think is pretty clear from your testimony yesterday and certainly clear from the expert report and reliance materials that you prepared in this case. So bear

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2 with me. We'll, I think, get through this pretty  
3 quickly.

4 MS. REISMAN: Mr. Carter, can you bring  
5 up Slide 9 from the Plaintiffs'  
6 demonstratives yesterday.

7 BY MS. REISMAN:

8 Q. Mr. Rafalski, this is the methodology  
9 that you described using in this case to reach the  
10 opinion that you set out in your expert report; is  
11 that correct?

12 A Yes, ma'am.

13 Q. Okay. So I'm going to try to do this in  
14 a summary fashion so that I can keep to my five  
15 questions.

16 THE COURT: Don't let me stop you.

17 MS. REISMAN: No, no, no. That's fine.

18 Your Honor, I can easily do this quickly.

19 BY MS. REISMAN:

20 Q. This is the methodology you say you  
21 used, and I just want to go through each of these  
22 bullet points here and talk to you about your  
23 performance of that with respect to Walmart.

24 The second bullet under the methodology  
25 you performed is to collect Defendants'

transactional data, correct?

A Yes.

Q. And am I correct that neither in your report, in the footnotes to that report, or in the reliance materials that you list in Schedule 1 to the report do you reference, review, or evaluate the Defendant Walmart's transactional data; is that correct?

A That's correct.

Q. And moving on to the third bullet, your review of the Defendants' compliance program in your methodology, am I correct that you neither reviewed nor reference nor evaluate any of Walmart's standard operating procedures?

A That is correct.

Q. And moving on to the next task under what you say you did to perform your methodology in reviewing Defendants' compliance programs, am I correct that nowhere in your report, your footnotes, or the Schedule 1 of your reliance materials do you reference, review, or evaluate any due diligence, documentation, or information suspicious ordering monitoring program information or any know-your-customer materials for Walmart?



1                   A       That's correct. There's nothing in my  
2  
3       report that is a review of any Walmart material or  
4       any opinions.

5                   Q.     And that would include investigations,  
6       interviews, and witness statements, which, as you  
7       noted yesterday, really takes the form of discovery  
8       responses in depositions, in addition to documents,  
9       did you reference, review, or evaluate any of those  
10      materials for Walmart?

11                  A       I did not.

12                  Q.     And the same for internal company  
13      communications and documents, did you reference,  
14      review, or evaluate any internal company  
15      communications and documents for Walmart?

16                  A       I did not.

17                  Q.     And the last task under your methodology  
18      for reviewing Defendants' compliance program, did  
19      you reference, review, or evaluate any prior  
20      administrative actions against Walmart?

21                  A       I did not.

22                  Q.     So the bottom line is, nowhere in your  
23      report do you reference, review, or evaluate any,  
24      any compliance program of Walmart, you offer no  
25      opinions on Walmart's program; is that correct?

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A Yes, that's correct. The Plaintiff attorneys have never asked me to review anything related to Walmart as of today's date.

Q. Okay. And if we just move to the last bullet of your methodology on Slide 9 of the demonstrative from yesterday, the review of data resulting from metric applied by a data analyst, that would be what you have in your Schedule 2 to your report that you received from Dr. McCann; is that correct?

A That is correct.

Q. And do you reference, review, or evaluate any Walmart data in that schedule or in your report at all?

A I do not.

Q. So in preparing your opinions in the case, you didn't apply your own methodology to reach any opinions on Walmart or to apply any of your general opinions about effective controls against diversion and suspicious order monitoring to Walmart; is that correct?

MS. CONROY: Objection, your Honor.

A That is correct.

MS. CONROY: Your Honor, he's already

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2 acknowledged that Walmart is not a part of his  
3 report.

4 THE COURT: Okay.

5 MS. REISMAN: Your Honor, I have no  
6 further questions.

7 THE COURT: That's really not an  
8 objection. It's a comment. So she's  
9 correct.

10 Do you have anything further?

11 MS. REISMAN: No further questions, your  
12 Honor. Thank you, Mr. Rafalski.

13 THE COURT: Ms. Conroy, redirect -- Mr.  
14 Rafalski, I have a question.

15 THE WITNESS: Sure, your Honor.

16 THE COURT: Sometimes or most times when  
17 an expert is retained or a potential expert  
18 is retained, the expert suggests to the  
19 retaining attorney the information and  
20 documents they would like to look at.

21 Did that happen here?

22 THE WITNESS: Yes, sir.

23 THE COURT: So is it fair to say that  
24 you provided the requesting attorney,  
25 Plaintiffs' attorneys here, to forward you a

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list of things you would need in order to  
consider the commission?

THE WITNESS: Yes, sir. Could I provide  
a little more information on that?

Originally at the discovery, I met with  
the attorneys and I provided them -- we sat  
down and I asked what they needed to request  
the discovery. And then subsequent to that,  
I think they knew what they were going to  
provide me to form my opinions. So that  
would be yes, sir.

THE COURT: Okay. Thank you.

Ms. Conroy, I'm sorry.

MS. CONROY: Thank you, your Honor.

REDIRECT EXAMINATION

BY MS. CONROY:

Q. Mr. Rafalski, one of the first things  
that Mr. Schmidt did when he was examining you was  
to show the methodology slide that we had used and  
then he put some Xs on it; do you recall that?

A I do.

Q. And you were -- well, let me ask you,  
did you agree with those Xs that were on that --  
annexed to each of those bullet points?

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A No.

Q. And did you think it was unfair?

A I don't know if unfair. I know that federal regulations which --

MR. SCHMIDT: I don't think it's for the witness to say what's fair or unfair, your Honor. Improper question.

THE COURT: Who was that?

MR. SCHMIDT: Mr. Schmidt. I'm back on.

THE COURT: Was that Mr. Schmidt?

MR. SCHMIDT: Yes, it was, your Honor.

THE COURT: Say it again, please.

MR. SCHMIDT: I don't think the witness can testify about what he thinks is fair or not fair.

THE COURT: Generally you're right, but I'll let it go today.

Answer the question.

A I just don't think it was fully accurate. I don't know about being fair or unfair. I just know how the process works, so I didn't look at it in a fairness way.

BY MS. CONROY:

Q. And why wasn't it a -- why do you

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1 believe there should not have been an X next to  
2 those methodology bullet points?

3  
4 A I think some of the questions had a  
5 narrowness to them, or when you're required to  
6 provide a yes-or-no answer, some of the questions  
7 are complex answers where they have multiple issues,  
8 and it's just not as simple as a yes or no.

9 And my answers were specific to the  
10 questions, and then he applied them to a much  
11 broader topic in those bullet points.

12 Q. And when we were talking about your  
13 methodology in this case and the methodology that  
14 was applied by DEA agents, including yourself, there  
15 was never any indication that all due diligence  
16 files would be reviewed or all customer files would  
17 be reviewed; is that correct?

18 A Specifically my actions and the cases  
19 that I'm aware of, I've never seen where a case that  
20 moved forward on administrative action where every  
21 customer file was reviewed.

22 It was more of a sampling where there  
23 was a sufficient determination of company product,  
24 you know, company records, and it's not just -- when  
25 we talk about due diligence, everyone focuses on

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just the documents to a specific pharmacy, but it's bigger than that. It's the totality of circumstances.

It's emails, policies, depositions, witness statements, or in this case deposition responses to questions at depositions. So it's much broader than just talking about a piece of paper for a specific customer.

Q. And, you know, let me ask you something about that to sort of give an example of what you're talking about.

If you were a health inspector, and you walked into a restaurant and you saw two giant rats on the counter, would you have to go into the kitchen to determine if there were other rats there to make sure that you didn't have a violation?

MR. SCHMIDT: Objection.

Relevance.

A I could provide you a better analogy.

Q. Please do.

THE COURT: Time out.

A Okay. Never mind. I'm sorry.

THE COURT: You don't like the vermin analogy?

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MR. SCHMIDT: I would state why was that restaurant licensed if there was a restaurant with big rats? So I don't think it's a fair metaphor.

THE WITNESS: Maybe a pet rat.

THE COURT: Ms. Conway, I get it. Move on.

BY MS. CONROY:

Q. Mr. Rafalski, Mr. Schmidt referred to the time that you spent with the New York report over and over again; didn't he?

A Yes, he did.

THE COURT: 13-and-a-half hours, correct? Is that what you testified to?

THE WITNESS: Well, that's -- and he's looking at specific billing, your Honor. I think the day I started working on --

THE COURT: No, no, no. I just asked, it was 13.5 hours, your testimony?

THE WITNESS: For the billing, yes, sir.

THE COURT: Go ahead.

BY MS. CONROY:

Q. Mr. Rafalski, let's take a look at your testimony that Mr. Schmidt had you look at about



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2 that 13-and-a-half hours. And several times you  
3 went back and forth and said that was just one  
4 section of your billing; do you recall that?

5 A Yes, ma'am.

6 Q. So if we look at page 33 of your  
7 deposition, and I just want to have you read the  
8 rest of your answers on those pages.

9 Do you have the deposition there in  
10 Detroit?

11 A I do. One second, please.

12 Do you have a line, Ms. Conroy?

13 Q. I do. If you start at page 3 -- 33, I'm  
14 sorry, line 18.

15 THE COURT: Mr. Schmidt, do you have it?

16 MR. SCHMIDT: Yes, your Honor.

17 THE COURT: Okay, good. You don't have  
18 to stand up. I mean, I appreciate the  
19 courtesy, but you were standing up long  
20 enough yesterday and today.

21 MR. SCHMIDT: Thank you, your Honor.

22 BY MS. CONROY:

23 Q. And, actually, Mr. Rafalski, if you go  
24 up on that page a little bit, I believe what was  
25 shown to you was starting at line 10.

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The question: "The upper limit on time reviewing New York documents for your report was about 13.5 hours?"

And you responded: "I would say yes, sir."

And the question: "Next. Okay. And you understand you were reviewing documents corresponding to ten different Defendants in this case?"

And you responded: "Yes."

Do you see that?

A Yes, sir -- or yes, ma'am.

MR. SCHMIDT: Can you just tell me the page again?

MS. CONROY: 33.

MR. SCHMIDT: Thank you.

THE COURT: And the lines?

MR. CONROY: What I just showed you, it was lines 10 to 18, 17 or 18. I'm not sure what was actually shown on the screen during Mr. Schmidt's examination, but that's my recollection of what was shown.

And then if you would take a look, Mr. Rafalski, at lines 18 to the bottom of

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the page 24. So let me read you the question.

"So just a little more than an hour per Defendant; is that right?"

And then could you read your answer, sir.

THE WITNESS: "Well, so just for clarification, if I say review documents here, when I'm drafting, reviewing, making changes, I'm probably looking at documents all during that time."

BY MS. CONROY:

Q. And if you could turn the page to page 34, and there's really no question. It's just a question, Okay, on line 1. If you could read lines 2 through 10.

A "ANSWER: I think when the documents first come in to me, I had access. I believe it was the 9th, around the 9th, but I'm not positive.

And then I spent a little more time looking at specific documents and policies. Then once I was into the drafting, I would go back and forth between the drafts and the policy."

Q. Then there's a question, Okay, line 11.

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2 And then could you read 12 through 14, your answer.

3 A "ANSWER: I don't want to say the time  
4 is very accurate. My description might be just  
5 broad and whatever my duties were."

6 Q. And then the question on line 15:  
7 "Okay. So if we add in the time that you spent  
8 drafting and say maybe you spent some time reviewing  
9 documents while you're drafting, it's maybe two or  
10 three hours per Defendant?" And your answer?

11 A "Yes, sir."

12 Q. So it was more than 13-and-a-half hours,  
13 isn't that correct, for the review of the New York  
14 documents?

15 A Yes.

16 Q. And that is how you testified in your  
17 deposition?

18 A Yes.

19 Q. And would it surprise you to learn or  
20 maybe you know, do you know how many hours you had  
21 spent generally on this report up to the time the  
22 New York report was filed in December of 2019?

23 A I didn't go back and specifically look  
24 at the billing so I would -- oh, I'm sorry.

25 Q. Would it surprise you to learn that it's

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2 over 350 hours to complete your report which was  
3 marked as Plaintiffs' Exhibit 1 for identification?

4 A That would not surprise me.

5 MR. SCHMIDT: Objection, your Honor.

6 I think they're mixing two reports.

7 THE COURT: Okay. I don't know that,  
8 but, Ms. Conroy, would you respond to that.

9 Q. Are we mixing two reports, Mr. Rafalski?

10 A I know that it was more than 13-and-a  
11 half, your Honor. I don't know exactly that I agree  
12 or don't disagree with that number, it's probably  
13 based on some of the billings that I submitted.

14 Q. When Mr. Schmidt makes the comment that  
15 over 350 hours is related to a different report; is  
16 that correct?

17 A It might encompass I think some of the  
18 MDL report. I'm not sure it was specifically billed  
19 to New York, but as I testified before much of the  
20 New York report, a lot of the work from the very  
21 beginning, it's all corporate policies, and it's  
22 made consistent throughout the United States, so I  
23 would probably say, if you ask me much of my hours,  
24 much greater than 300 hours were also contributed to  
25 this New York report.

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1 Q. Exactly. And that's because you went  
2 and looked for each of the Defendants, you analyzed  
3 their suspicious order monitoring, protocols and  
4 procedures, you followed your methodology with  
5 respect to each one of the Defendants, and that's  
6 what we see when we look at your report, we see  
7 discussions of the nationwide compliance programs  
8 for each one of the Defendants, correct?  
9

10 A That's correct. The only thing I needed  
11 to do was just to confirm that there was not  
12 something specific to New York, and I found no  
13 policy that would indicate there was a deviation  
14 from the corporate policy or they were doing  
15 anything special in New York, and once that I was  
16 confident that that wasn't occurring, then I moved  
17 on.

18 Q. And so when you were working on your  
19 report and looking at those national policies, you  
20 were reading company internal documents, randomly  
21 selected due diligence files, you were reading  
22 witness testimony and depositions of corporate  
23 executives, all of those things were encompassed in  
24 the 350-or-so hours to develop your opinions with  
25 respect to the nationwide compliance program,

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correct?

MR. SCHMIDT: Your Honor, I'm trying to be mindful of what you said about leading and only objecting to leading on important points. These last couple of questions are just the lawyer testifying. Leading.

THE COURT: Sustained.

Q. Mr. Rafalski, can you explain the hours that were spent and the type of -- strike that.

Can you describe for me the types of information that you looked at pursuant to your methodology to develop your opinions in this report concerning the national compliance programs for the Defendants.

A First and foremost to me were the written policies. Those were policies that were accepted and adopted by each of the Defendants. I think those policies speak for themselves.

Second would be the review of internal documents. Sometimes there's draft policies, communications about the policies. There's emails that may discuss the policy. I would also look at those documents.

There may be beta testings of things

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2 discussed in the policies, and then I would look to  
3 see where the deviations were in the policy or the  
4 failures to follow those policies.

5 To me the integral part of each  
6 corporation was if they had a policy and if they  
7 followed it, or if they had no policy, then it  
8 became a little more complex, because I would try to  
9 understand what they did if they had no written  
10 policy, how they actually accomplished the task in  
11 complying with the regulation of the law.

12 Q. Thank you.

13 Now, Mr. Schmidt spent quite a bit of  
14 time with a document that was marked as Defendants'  
15 Exhibit C, which was a comparison of your report and  
16 the New York Attorney General's first amended  
17 Complaint; do you recall that?

18 A I do.

19 Q. And do you have exhibit, Defendants'  
20 Exhibit C handy?

21 A I do. One second, please.

22 THE COURT: It's C, correct?

23 THE WITNESS: I'm ready when you are,  
24 your Honor.

25 MS. CONROY: Your Honor, I would like to



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2 put it on the screen, and I think we're just  
3 trying to figure out how to get Defendants'  
4 Exhibit onto the screen. There we are.  
5 Thank you.

6 Q. Now, Mr. Schmidt -- if you can go to the  
7 next page, Mr. Lawler (phonetic).

8 THE COURT: You said Mr. Schmidt.

9 MS. CONROY: Mr. Lawler is the man in  
10 the back.

11 And the next page.

12 Q. Now, Mr. Schmidt called this a cut and  
13 paste from the State's Complaint over to your  
14 report, and here's the first page of the Amerisource  
15 opinion; do you see that?

16 A I do.

17 Q. And for some reason Mr. Schmidt didn't  
18 want to recognize all of your footnotes.

19 MR. SCHMIDT: There's somebody's open  
20 mic, I can't --

21 MS. LICARDI: I just muted them.

22 MR. SCHMIDT: Okay. Go ahead. Sorry.

23 Q. Mr. Rafalski, this wasn't just a cut and  
24 paste, was it, because take a look at your report  
25 section, there are footnotes there, correct?

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A Yes, Ms. Conroy.

Q. And what -- tell us your process again and why you inserted footnotes as you went through and added these facts to your report.

A So the document on the right was -- came to me in a draft form, and I would read these, and I would make a decision on whether to adopt them or not, you know, the relevance.

And I think, as I testified before, I think they're all kind of factual situations that was more resolved of the compliance issues, but when I read them I found them to be potentially something I would add to my report.

The problem is is that I learned in this process that I just don't make statements unless I apply, I have to reference the information, and so I would go back, not to New York, but I had a contact person that went in between Mr. Elkins (phonetic), and I would send this to Mr. Elkins. Sometimes in a fashion I'd highlight and make notations and send it back and forth and said I can't use this unless I have the verifying documents, and once I got the documents I would review the content of the documents and then I would make a decision on

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whether to accept them or not to accept them.

And so what you see in the footnotes, that just means that -- to me that meant that, you know, I think I tried to testify that I reviewed them and added the footnotes to substantiate some of the statements or the statements that I think that I needed to be supported by the reference.

THE COURT: Can someone display the footnotes for the Court, please. That's 286 to 287.

Q. So in Exhibit 1, Mr. Lawler, if you go to Plaintiffs' Exhibit 1, which is the expert report, and we look at page 72.

MS. CONROY: Your Honor, you can see the -- I don't know if you can actually see it, but we can pull some of those, if you like, but you can see.

THE COURT: 286 Sherman-Hynes, examination pages 36 to 37, and 287 is ABDC -- a lot of letters. This is from the MDL, House Committee on Energy and Commerce, supra note 556 at 184. Okay.

Q. And, Mr. Rafalski, if you look at this and in order to support the sentence -- if I can

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2 find it here -- 286, Mr. Lawler, it's up at the top,  
3 right under -- it's the third sentence in the first  
4 paragraph from 2007 to 2015. The program specifics  
5 were scattered through a series of policy and  
6 procedure documents, and then we see footnote 285,  
7 and if we look down at the bottom, and we can pull  
8 up this document during the lunch break, but this is  
9 a document produced by AmerisourceBergen with that  
10 Bates number.

11 Is that familiar to you, Mr. Rafalski?

12 A Yes, ma'am.

13 Q. And so before you added the sentence  
14 concerning the AmerisourceBergen program specifics,  
15 you took a look at that AmerisourceBergen document  
16 that is footnoted at 285; that's your methodology,  
17 correct?

18 A Yes.

19 Q. And if you go to the next footnote where  
20 it says that the policies and procedure documents  
21 which were not uniform for Bellco and Amerisource --  
22 let me ask you this. What is Bellco?

23 A Bellco was a company that was acquired  
24 by Amerisource. So it was actually, I guess it  
25 would be considered a subsidiary of Amerisource, but

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there was a period of time where they were operating as two different entities to distributors.

Q. And you went back and looked to determine what was or was not uniform for Bellco and Amerisource, the Sherman-Hynes deposition, and you list the pages where Sherman-Hynes testified about that, correct?

A Yes.

Q. And that was part of your methodology in preparing this report, that you didn't just accept facts as they were provided to you, even if they were from a complaint written by the New York State Attorney General's office, you went and looked yourself, correct?

A That's correct.

Q. And that is true throughout your report, correct?

A Yes.

Q. So it wasn't just for the sentences that were isolated in Defendants' Exhibit C, with respect to the New York AG's Complaint, when I look through your report, Exhibit 1, almost every sentence, certainly every paragraph is footnoted; do you see that?

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2 MR. SCHMIDT: Objection.

3 Foundation.

4 Q. Are you looking at the report?

5 THE COURT: Wait. There's an objection.

6 Overruled.

7 Go ahead.

8 Q. Are you looking at the report?

9 A Yes, I'm sorry, I was waiting for the  
10 objection.

11 Yes, you said "almost every sentence."  
12 I'm not sure it's almost every sentence, but there  
13 is a significant amount of footnotes contained in  
14 the report.

15 Q. How many footnotes? Can you take a look  
16 at page 166.

17 A 906.

18 Q. Now, let's take a look at your  
19 deposition testimony.

20 Mr. Schmidt had referred you to it, page  
21 496 of your February 7th deposition. And if you  
22 take a look -- now, if you go to page 496, line 11,  
23 and I believe is it your recollection that that was  
24 read to you, line 11 through 17, by Mr. Schmidt?

25 A You want me to read the question, I'm

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2 sorry?

3 Q. My question is do you recall when that  
4 was read yesterday?

5 THE COURT: Ms. Conroy, it doesn't  
6 matter.

7 MS. CONROY: Okay.

8 THE COURT: If you wish to question,  
9 answer, question, answer, you're permitted  
10 to. Of course you know you're permitted to  
11 reference any part of the deposition during  
12 your redirect.

13 MS. CONROY: Yes, your Honor. Thank  
14 you, your Honor.

15 THE COURT: As long as it's in the scope  
16 of the cross.

17 MS. CONROY: Thank you.

18 Q. If you would take a look at line 18  
19 through the end of that page 496. The question is:  
20 "So you didn't review all of the footnotes in this  
21 report?"

22 And then your answer, if you could read  
23 it.

24 A (READING:) I am not definitive about  
25 that. I tried, but I'm not positive of that. I

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2           should have probably kept some record of each one or  
3           checked them off as I started writing, and I said my  
4           book, which was discussed later, and I believe I  
5           did -- and on to the next page -- but I'm not  
6           positive.

7                   Q.     And on page 497, lines 2 through 4, the  
8           question is: (READING:) And just to clarify, when  
9           we say -- when I say check the footnote, I mean  
10          review the document; that's it?

11                          And your answer on line 5?

12                   A     (READING:) Yes.

13                   Q.     "QUESTION: Citing, right?"

14                          And then your answer, if you could read  
15          it, lines 11 through 10 -- I'm sorry, 7 through 10.

16                   A     (READING:) Yes. Company report. Have  
17          the report. Open up the document, review it and the  
18          content. Make sure that I agree with it, what it  
19          says, and then move on.

20                   Q.     And the question, line 11 to 13.

21                          (READING:) Okay. But you're not aware,  
22          sitting here today, if you did that for every  
23          footnote in this report?

24                          And your answer at line 16, if you could  
25          read that.



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2 A (READING:) I'm not positive, because if  
3 I missed one or two I don't want to be incorrect.

4 Q. So what we're talking about from your  
5 testimony that day and your memory is that of the  
6 906 footnotes, you may have missed out on reading  
7 one or two; is that correct?

8 A Yes, ma'am.

9 Q. The rest of the footnotes were all  
10 reviewed and analyzed by you and used as support for  
11 the opinions in your report and the facts that  
12 support those opinions, correct?

13 A Yes, ma'am.

14 Q. Mr. Schmidt spent quite a bit of time  
15 going through Defendants' Exhibit C, which is the  
16 comparison of the State Complaint paragraphs and  
17 your report.

18 Did he find fault with any of the  
19 factual support for any of the statements in your  
20 report?

21 A No, ma'am.

22 MR. SCHMIDT: Objection, your Honor.

23 THE COURT: Time out. Can I have that  
24 question?

25 Did you say did he find fault?

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2 MS. CONROY: Did Mr. Schmidt, during his  
3 examination, find fault with any of the  
4 actual facts of the report.

5 THE COURT: I'll sustain that. Mr.  
6 Schmidt is not a witness; he's an advocate.

7 Was he obligated to stand up and say, by  
8 the the way, I find fault? No, he was not.

9 MS. CONROY: I understand, your Honor.  
10 Thank you.

11 Q. This morning, Mr. Rafalski, Mr. Schmidt  
12 referred to the Federal Register.

13 Do you have that in front of you? I  
14 believe it was marked as Defendants' Exhibit H.

15 THE COURT: H?

16 MS. CONROY: H.

17 A If that is the one that addresses the  
18 quota diversion, I don't have that.

19 MS. CONROY: Is it possible for Mr.  
20 Lawler to put it up on the screen. And if  
21 you could go to page 173 and if you could --  
22 perfect. Perfect.

23 Q. Mr. Rafalski, you were shown this this  
24 morning, you didn't have an opportunity to study it;  
25 is that correct?

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2 A That's correct.

3 Q. If we could just take a look over on the  
4 first column where it says: Estimates of diversion  
5 pursuant to the Support Act; do you see that?

6 A Yes, ma'am.

7 Q. And this is to determine -- or this  
8 attempts to describe how diversion is estimated and  
9 it says -- I'm just reading the first sentence there  
10 -- To estimate diversion, as is required by the  
11 Support Act, DEA aggregated the API of each covered  
12 controlled substance by metric weight where the data  
13 was available in the aforementioned databases.

14 Now, what I want to focus your attention on  
15 is the next sentence.

16 (READING:) Based on the individual  
17 entries into the aforementioned databases, DEA  
18 calculated the estimated amount of diversion by  
19 multiplying the strength of the API.

20 And then it goes on to describe how the  
21 formula works.

22 Do you see that?

23 A Yes, ma'am.

24 Q. And then if you take a look on the  
25 second column, do you see the calculation, what that

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1 estimate -- there it is. Right there. Those  
2 numbers. That is the actual calculation for 2018.  
3 Do you see that?  
4

5 A Yes, ma'am.

6 Q. But then if we take a look over on the  
7 third column in the paragraph that begins, As  
8 discussed above, there's more discussion of what it  
9 is that the DEA -- the actual databases and  
10 information that the DEA is using to make those  
11 estimations, and if you would -- I'll read that  
12 paragraph out loud.

13 (READING:) As discussed above, DEA  
14 considers the extent of diversion of all controlled  
15 substances and estimates diversion of covered  
16 controlled substances as is required by the recent  
17 amendment to the CSA and changes the DEA's own  
18 regulations.

19 The information maintained in the  
20 various DEA databases discussed above assist the  
21 agency in identifying some forms of diversion of  
22 controlled substances.

23 Do you see where it says "some forms of  
24 diversion"?

25 A Yes, ma'am.

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2 Q. Do you have any idea which forms of  
3 diversion are used for the estimation the DEA is  
4 making in this Federal Register?

5 A I do not.

6 Q. Do you have any idea of what forms of  
7 diversion are not accounted for in this Federal  
8 Register?

9 A From my -- while working as a diversion  
10 investigator there was never -- I always question  
11 why there was never a program just to account for  
12 the diversion that were identified through  
13 investigations or administrative actions. That to  
14 me was just one area where they could have  
15 accumulated some data to give some idea, but I do  
16 not know.

17 Q. So is it fair to say that we don't know  
18 right now if, for example, a distributor had a  
19 suspicious order monitoring system that failed to  
20 account for threshold when thresholds were exceeded  
21 or they did no due diligence at all, that, as far as  
22 you know, would not be accounted for in this  
23 diversion estimate?

24 MR. SCHMIDT: Objection.

25 Leading.

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2 THE COURT: Overruled.

3 A Yes, I don't know exactly how they came  
4 up, without looking at this study or maybe  
5 discussing it with someone, I have no idea how they  
6 came up with those numbers that they utilized in  
7 this report in setting this quota.

8 Q. And all we do know is that some forms of  
9 diversion were not accounted for in this estimation,  
10 correct?

11 A I think that is very probable looking at  
12 the numbers.

13 Q. Okay. And also very probable looking at  
14 what it says right there on the page, correct?

15 A Yes.

16 MR. SCHMIDT: Objection.

17 It's a misread of the document.

18 THE COURT: Objection?

19 MR. SCHMIDT: To foundation.

20 THE COURT: But the document has been  
21 produced. I'll allow it.

22 MR. SCHMIDT: I agree.

23 Q. And if you could read the final sentence  
24 in that paragraph just below the highlighting.

25 A (READING:) The DEA is committed to

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2 improving its ability to account for other types of  
3 diversion.

4 Q. So it's a work in progress, correct?

5 A Yes, it is.

6 THE COURT: Just so you know, the Court  
7 will consider the document for what it  
8 actually says as opposed to any  
9 interpretation of it, in the absence of it  
10 being confusing. It's not confusing.

11 MR. SCHMIDT: Thank you, your Honor.

12 MS. CONROY: Thank you, your Honor.

13 Q. Mr. Rafalski, there was an objection  
14 yesterday by counsel that you had disclosed  
15 confidential information when talking about a  
16 Mallinckrodt investigation; do you recall that?

17 A Yes, ma'am.

18 Q. And did you disclose any confidential  
19 information during your testimony yesterday?

20 A I do not believe I did. I think  
21 everything I discussed was a person could find  
22 through information available outside of DEA,  
23 internal DEA.

24 Q. And isn't it also the case that the  
25 public press release is also a footnote to your

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report?

A It is. More significant in the Mallinckrodt was there was, unfortunately, a leaked document, a complaint, a draft complaint. There was an article in the Washington Post that gave a lot of internal information, too, and that's readily available to the public.

Q. If we could just go back to footnotes for a bit. Take a look at your report, which was Exhibit 1, and if you take a look at page 25 of your report.

A One second. I have limited room, and I have a lot of documents here.

Okay. Page 25. I'm there.

THE COURT: Wait a second, sir. They're putting it up.

Q. And do you see the center of the page, it says: DEA administrative actions?

A Yes, ma'am.

Q. What is an administrative action?

A That's an action that the DEA takes for violations of the Code of Federal Regulations.

Q. And if we take a look, you have a long list of DEA administrative actions that stem -- that



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2 go from page 25, all the way through page 35.

3 Do you see that?

4 MR. SCHMIDT: Objection.

5 Well outside the scope of my cross.

6 THE COURT: Okay. You heard the  
7 objection.

8 MS. CONROY: I did. We're discussing  
9 the support for his report, the methodology,  
10 seem to be squarely within the  
11 cross-examination.

12 THE COURT: Mr. Schmidt, did you hear  
13 the response?

14 MR. SCHMIDT: Yes. I think there's a  
15 substantive point --

16 THE COURT: She's suggesting it goes to  
17 methodology.

18 MR. SCHMIDT: Yes, I don't think it  
19 does. I didn't ask for the section of the  
20 report. I think Ms. Conroy is trying to make  
21 a substantive point here regarding the  
22 administrative actions under the ruse of  
23 talking about methodology. This has nothing  
24 to do with anything I asked him about.

25 THE COURT: Ms. Conroy?

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MS. CONROY: I am not.

THE COURT: Beg your pardon?

MR. SCHMIDT: I apologize, could I say  
one more thing, your Honor?

THE COURT: Go ahead.

MR. SCHMIDT: I think the point has  
already been made about the footnotes. It  
would be cumulative anyway, but I don't think  
that's the purpose of this exam.

MS. CONROY: This is not a ruse, your  
Honor. The cross-examination took --

THE COURT: I want to see the report.  
Hang on a second.

Okay. Apparently, the document sets  
forth, beginning on page 25, into the terms  
and conditions resulting from the  
administrative action; is that correct,  
everybody?

MS. CONROY: Yes, your Honor.

THE COURT: Okay.

MR. SCHMIDT: Yes.

THE COURT: And Mr. Rafalski --

THE WITNESS: Yes, sir, your Honor.

THE COURT: In connection with

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methodology and the means to fulfill all the steps of the methodology, what significance, if any, is this document that we're talking about, these pages we're talking about, regarding DEA administrative actions?

THE WITNESS: Two things, your Honor. One, you started with the review to look at the history of the different companies; and then secondly, a part of my experience with the DEA is companies closely monitor administrative actions against other registrants, especially the ones that are published in the public register.

But secondly, their law firms and consulting firms and all others, analysis, and it was also to show that all of these actions, there was awareness of the diversion and the issues with suspicious orders and due diligence and these kind of administrative matters.

THE COURT: Okay. And, Ms. Conroy, you're offering it as part and parcel of the methodology?

MS. CONROY: I am, your Honor. But in

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particular, we went over for almost two hours some really disparaging comments about cutting and pasting, and what we're showing here is that the statements in the report and that were made throughout were footnoted and that were significant, and here we have DEA administrative actions, which are all footnoted as support.

THE COURT: And have you shown me where they're footnoted? Will you show me where they're footnoted.

MS. CONROY: Yes. Each time one is referenced there's a footnote at the bottom.

MR. SCHMIDT: And, your Honor, this appears nowhere in the section in the exhibit that I used with the cutting and the pasting or in my questions, and my concern in making this objection, my biggest objection is that we're now doing a substantive exam on administrative actions. I don't get recross. So they chose not to ask this on direct, I didn't ask it on cross, and now it's a new topic on recross.

It doesn't relate to -- they already

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2 covered the fact that this section and every  
3 other section is footnoted, so the only  
4 purpose of this section is to point out  
5 administrative actions that I don't get to  
6 recross on.

7 THE COURT: Mr. Rafalski, leave it at  
8 this. Is it fair enough or is it accurate  
9 that you footnoted this DEA administrative  
10 actions' language in your report? Yes?

11 THE WITNESS: Yes, sir. Everyone of  
12 them should have a supporting document  
13 footnote.

14 THE COURT: Just stop right there.  
15 Let's move on. You can leave it at that.

16 MS. CONROY: Thank you, your Honor.

17 Your Honor, it's just about -- we've got  
18 about ten more minutes before lunch. Can I  
19 consult with Nassau County and the State to  
20 make sure that there aren't any additional  
21 points that we wish to make?

22 THE COURT: Okay.

23 MS. CONROY: Can I do that right now?

24 THE COURT: Yes. How much time do you  
25 need?

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2 MS. CONROY: Well --

3 THE COURT: If we can finish Mr.  
4 Rafalski before I take the lunch break, that  
5 would be fine.

6 MS. CONROY: Great. If you would just  
7 give me -- go out of wherever these mics are.

8 THE COURT: I'll go take a walk.

9 MS. CONROY: Okay. Thank you.

10 MR. HANLY: Your Honor, it's Paul Hanly,  
11 for the Plaintiffs.

12 THE COURT: How are you?

13 MR. HANLY: I'm fine.

14 We have a significant team of folks that  
15 have input, and we just don't think it's  
16 going to be possible to finish in three  
17 minutes.

18 THE COURT: We'll see you at two  
19 o'clock.

20 MR. HANLY: Thank you, your Honor.

21 THE COURT: By the way, before we go off  
22 the air, floating around the system here is a  
23 Summons with Notice, I think you've all seen  
24 it, a Summons with Notice that the Plaintiffs  
25 have described as virtually every fire

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district on Long Island, every township on Long Island, a bunch of villages on Long Island.

Now, early on we received what appeared to be a Complaint, not a Verified Complaint, which the Court rejected and sent back. I understand, and I'll confirm later, that subsequently a Summons with Notice was filed, and I'll call it in that matter.

If it's, in fact, floating around, the Court intends to call a conference for purposes of either a preliminary conference order or something else to get a handle on it, because I think -- Sandy, what did we count, I think about 130 people, 130 Plaintiffs?

MS. LICARDI: 73 Plaintiffs, but no RJI was signed.

MS. SHKOLNIK: If I'm not mistaken, your Honor, we had that quick hearing. It popped up. Would you like us to reach out to counsel and find out the status and report?

THE COURT: Yeah, that would be fine.

MR. SHKOLNIK: We'll do it by tomorrow.

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2 THE COURT: Ms. Conroy, two o'clock.

3 MS. CONROY: Yes. Thank you, your  
4 Honor.

5 (WHEREUPON, after a luncheon recess, the  
6 following was had:)

7 THE CLERK: Come to order. Supreme  
8 Court, Part 48 is back in session.

9 THE COURT: Thank you. Good afternoon.

10 THE CLERK: Good afternoon, your Honor.

11 THE COURT: Please be seated. Okay.

12 THE CLERK: Mr. Rafalski, I remind you  
13 you're still under oath.

14 THE WITNESS: Thank you.

15 THE CLERK: Mr. Rafalski, I'll remind  
16 you you're still under oath.

17 THE WITNESS: Thank you. I understand.

18 THE COURT: Okay.

19 CONTINUED REDIRECT EXAMINATION BY

20 MS. CONROY:

21 MS. CONROY: Hello, Mr. Rafalski.

22 THE WITNESS: Hi.

23 MS. CONROY: If I could have Cory put up  
24 the methodology slide, please.

25 Thank you.



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2 Q. Now, Mr. Rafalski, if I could direct you  
3 to the final slide -- sorry. I don't think that's  
4 the correct slide.

5 Could we go to the exhibit, to the  
6 PowerPoint set that we had yesterday.

7 I apologize, your Honor.

8 THE COURT: It's okay.

9 MS. CONROY: Thank you.

10 Q. Do you see that, Mr. Rafalski?

11 A Yes, ma'am.

12 Q. Okay. Do you see this was an attempt to  
13 sort of lay out on one slide your methodology that  
14 you conducted in this case, correct?

15 A Yes, ma'am.

16 Q. And the last bullet point is review of  
17 data resulting from metric applied by data analysts;  
18 do you see that?

19 A Yes, ma'am.

20 Q. Now, you asked data analysts to apply  
21 some of the metrics to transactional data; is that  
22 correct?

23 A In the litigation, yes, ma'am.

24 Q. And that is consistent with what you did  
25 at DEA as well, you used data analysts to implement

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1 metrics or algorithms or formulas on data that was  
2 provided by companies?

3  
4 A It was one of the methodologies. It was  
5 not used in all cases but it would be typical of  
6 something that I would do, if required, for an  
7 investigation.

8 Q. Now, could we turn to the slide that  
9 references your five metrics in this case.

10 And you see they're somewhat confusing  
11 words there, but you recognize those five different  
12 metrics as the metrics that were applied by a data  
13 analyst in this case, correct?

14 A Yes, ma'am.

15 Q. Okay. Now, you asked for those five  
16 metrics to be run because that is what you did at  
17 DEA, correct, not necessarily those particular  
18 formulas, but that was your -- that was your  
19 methodology at DEA and your methodology here in this  
20 case?

21 A Yes. They're both consistent with the  
22 methodology I would use in my employment and similar  
23 to the methodology used here.

24 Q. Now, the first one, maximum monthly  
25 trailing six-month threshold. Is there an easier

1 Opioid Frye Hearing/Mr. Rafalski 131

2 way to talk about that one?

3 A Yeah. I think we've talked about that a  
4 lot. It's basically the system monitors the  
5 previous six months, and if the purchases in the  
6 current month exceeds the greatest amount in one of  
7 the previous six months, it triggers a suspicious  
8 order.

9 Q. And does that metric come from the  
10 Masters case?

11 A Yes, ma'am.

12 Q. And the Masters case, the Court will  
13 recall, was the case that you were the lead  
14 investigator on while at DEA, correct?

15 A Yes, ma'am.

16 Q. And that's the case that went all the  
17 way up to the DC Court of Appeals and was approved,  
18 correct?

19 A Yes, ma'am.

20 Q. And now the other four metrics that we  
21 see there, and I won't read them out, but those,  
22 those are all metrics that you identified for the  
23 data analysts, correct?

24 A Yes, ma'am.

25 Q. And those metrics come and were reviewed

1                   Opioid Frye Hearing/Mr. Rafalski                   132  
2           by you from the Defendants' files, correct?

3                   A       Yes, ma'am.

4                   Q.     And that is consistent with what you did  
5           at DEA, you would look to the metrics or the formula  
6           or the algorithm?

7                   THE COURT:   Time out.

8                   Is this a consistent method you employed  
9           while at the DEA; yes or no?

10                  THE WITNESS:   Yes.

11                  THE COURT:   Okay.   There's five metrics  
12           here.   When do you decide which one to use or  
13           do you use more than one or do they prove  
14           each other?

15                  THE WITNESS:   Typically at DEA, your  
16           Honor, generally you would apply the metric  
17           for that particular company.   You apply their  
18           own formula to see if they were following  
19           their own system to identify orders.

20                  In this case -- go ahead, I'm sorry,  
21           your Honor.

22                  THE COURT:   So you're telling me each --  
23           are you telling me that in this case and only  
24           this case, each company applies one of these  
25           five metrics or are there more metrics out

1 Opioid Frye Hearing/Mr. Rafalski 133

2 there?

3 THE WITNESS: There's an unlimited  
4 number of metrics.

5 THE COURT: Okay.

6 THE WITNESS: In this case, these are  
7 the metrics. The bottom four are the ones I  
8 identified in the investigation, and they  
9 were applied to the companies in the  
10 investigation, the top one I picked. These  
11 were all used in the real world by some of  
12 the companies in the -- in my -- contained in  
13 my report.

14 THE COURT: Okay. I got it.

15 MS. CONROY: You can take that slide  
16 down. Thank you.

17 Q. Mr. Rafalski, there's been a lot of talk  
18 about suspicious orders in the Masters metric that  
19 identifies -- that actually identifies individual  
20 suspicious orders that should have been investigated  
21 by a distributor, Masters, correct?

22 A Yes. An order.

23 Q. I'm sorry, I missed --

24 A Yes. It identifies an order that would  
25 violate the rule, the greater than any of the

highest six-month totals for the purchases.

Q. And if we could go to something that Mr. Schmidt brought up, the recurrent flags, why does your methodology apply recurrent flags to the data?

A It's, it's based on DEA guidance and it's just based on the fact that once the system identifies a suspicious order, if there's nothing done to dispel the order, if it's just shipped and there's no review, then it considers that all of the subsequent orders are suspicious.

And we talked about due diligence, and I think I stated earlier it's a totality of circumstances. It's not just looking at one, you know, like a one file or one piece of paper. It's -- you know, my opinion was based on a review of many things, including the customer file, to see if there was a -- an order was clear by due diligence, and here there was a systemic failure during the time period, so there wasn't a need to look at that specific order.

Q. Now, I would like you to assume that the DEA produced a government witness to officially speak on behalf of the DEA, similar to a 30B6 deposition or, your Honor, what we would recognize

1 Opioid Frye Hearing/Mr. Rafalski 135  
2 as an 11F witness.

3 And I would like to play a clip, very  
4 short clip from that deposition of Mr. Thomas  
5 Prevoznik, P-R-E-V-O-Z-N-I-K, who, at least at the  
6 time of his testimony, was Section Chief of  
7 Pharmaceutical Investigations.

8 MR. SCHMIDT: Objection.

9 THE COURT: You say objection. It seems  
10 to me like the question is framed as a  
11 hypothetical. Is it Miss Conroy? Are you  
12 framing it as a hypothetical?

13 Because when you lead a question I want  
14 you to assume in court when there's a  
15 proffered expert it signifies that it's a  
16 hypothetical. If it's a hypothetical, it  
17 counts only if, either now or later, the  
18 assumed facts are placed in evidence.

19 MS. CONROY: Yes, it is a hypothetical,  
20 and I'd like to put those facts into evidence  
21 with this clip.

22 THE COURT: Stay on guard. I'm going to  
23 allow her to reframe the question. Stay on  
24 your toes, as you always are.

25 Go ahead.

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2 Q. Mr. Rafalski, I would like you to assume  
3 that the DEA has a methodology and a position with  
4 respect to recurrent flags, and I'd like to show you  
5 a video testimony of a witness from DEA.

6 A Okay.

7 MR. SCHMIDT: Objection.

8 THE COURT: Your about to show a witness  
9 video testimony, right?

10 MS. CONROY: Yes.

11 THE COURT: Does the other side have  
12 this?

13 MS. CONROY: Yes. It was listed on our  
14 list of exhibits, your Honor.

15 THE COURT: All right, you can play it.

16 MR. SCHMIDT: Your Honor --

17 MS. CONROY: And I will give you the  
18 page and line if that's --

19 THE COURT: Mr. Schultz (sic), you were  
20 about to say something.

21 MR. SCHMIDT: Schmidt, your Honor.

22 THE COURT: I'm sorry. Schmidt. I'm  
23 sorry.

24 MR. SCHMIDT: That's okay.

25 What I'm trying to say is, number 1, I



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2 think it's an improper hypothetical to say I  
3 assume something and then try to show it to  
4 him; two, foundation. He didn't review his  
5 full testimony. I should have, at least,  
6 have a transcript, just in the same way that  
7 I extended Miss Conroy that courtesy. I just  
8 didn't flash up a video that couldn't be  
9 confirmed.

10 THE COURT: Okay. Miss Conroy, why  
11 don't you do it this way.

12 You know the contents of this video,  
13 right?

14 MS. CONROY: Correct.

15 THE COURT: Is it long?

16 MS. CONROY: No, your Honor. It's about  
17 30 seconds.

18 THE COURT: Then frame the question this  
19 way. Ask the witness to assume the following  
20 facts, all right, and as best you can, tell  
21 me what's on the video.

22 Q. Mr. Rafalski, I would like you to assume  
23 that the DEA believes that when a wholesale  
24 distributor gets a flag for a suspicious order and  
25 then that they determine it to be a suspicious

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1  
2 order, that they block that shipment, that they  
3 should terminate all future sales to that same  
4 customer until they are able to rule out diversion  
5 as occurring. I would like you to assume that fact.

6 THE COURT: Assume that it's assumed,  
7 now ask the question.

8 Q. Do you know if the DEA has taken any  
9 position with respect to that assumption?

10 A Yes, I do.

11 MS. CONROY: I'd like to confirm that.

12 THE COURT: Yes.

13 MS. CONROY: And it is page 77 -- I'm  
14 sorry, 771, line 10 to line 20 of the Thomas  
15 Prevoznik deposition that is attached to our  
16 list of exhibits provided to Defendants a  
17 week ago.

18 MR. SCHMIDT: Can you hand that around,  
19 please. I might have it. If you could send  
20 that around I'd be grateful.

21 MS. CONROY: We're happy to send it  
22 around as well.

23 MR. SCHMIDT: Thank you.

24 THE COURT: I'm waiting for something,  
25 right?

1 Opioid Frye Hearing/Mr. Rafalski 139

2 MS. CONROY: Right. We're waiting for  
3 it to play. We're waiting longer than the  
4 length of the clip...

5 (VIDEO PLAYING:

6 Q. Do you agree that if a wholesale  
7 distributor gets a flag of a suspicious order, that  
8 they determine to be a suspicious order, and that  
9 they blocked that shipment, that they should  
10 terminate all future sales to that same customer and  
11 so they can rule out that diversion is occurring?

12 Yes, I would agree that is a --)

13 MR. SCHMIDT: It's hard to say, your  
14 Honor. I still don't have the clip, so I  
15 can't tell if there's completeness that would  
16 be appropriate, but I think it's probably  
17 best at this point to move on.

18 THE COURT: We'll move on.

19 Q. Mr. Rafalski, I'd like you to assume  
20 that a registrant has a duty to block suspicious  
21 orders once they have been identified; is that all  
22 right?

23 A Yes.

24 Q. Okay. And I would like to play a clip  
25 with respect -- very short clip with respect to that

1                   Opioid Frye Hearing/Mr. Rafalski                   140  
2           same issue, also Thomas Prevoznik, Section Chief of  
3           Pharmaceutical Investigations at DEA.

4                   MR. SCHMIDT:   And I'll object.  
5           Foundation.

6                   And your Honor said pretty clearly to  
7           us, don't do substance. This seems pure just  
8           play their favorite videos and ask Mr.  
9           Rafalski to agree.

10                  THE COURT:   Do it the same way as you  
11           did before.

12                  MS. CONROY:   Yes, your Honor.

13                  THE COURT:   Phrase it as a hypothetical,  
14           give me the facts and play the video.

15           Q.    I'd like you to assume, Mr. --

16                  THE COURT:   One second. By the way, you  
17           realize in your Stipulation that you all  
18           worked out, any objections here, any evidence  
19           that makes its way into this record is  
20           subject to objection at trial, right?

21                  MS. CONROY:   Absolutely.

22                  THE COURT:   You can all reserve all your  
23           rights, all right? Good.

24                  MS. CONROY:   Yes, yes.

25           Q.    I'd like you to assume that a registrant

1                   Opioid Frye Hearing/Mr. Rafalski                   141  
2           has a duty to block suspicious orders when they are  
3           identified as suspicious.

4                   Do you accept -- I'm sorry. I lost Mr.  
5           Rafalski.

6           A       I'm here. I accept that, yes.

7                   MS. CONROY: And I would like to play a  
8           clip from Mr. Thomas Prevoznik, from DEA, and  
9           the page is also page 771. It's all one  
10          page.

11                  MR. SCHMIDT: What's the line number,  
12          please?

13                  MS. CONROY: The line number 10 through  
14          20 -- I'm sorry, 7. 7 through 20.

15                  (VIDEO PLAYING:

16           Q.     Does the DEA take the position that a  
17          registrant of controlled substances has a duty to  
18          block shipments of suspicious orders?

19                  Yes.

20                  Is that now and always been the law in  
21          the United States of America?

22           A       Yes.)

23                  MS. CONROY: I have no further  
24          questions, your Honor.

25                  THE COURT: Mr. Rafalski, I have one or

1 Opioid Frye Hearing/Mr. Rafalski 142

2 two follow-up questions.

3 Those five metrics that you pointed  
4 out --

5 THE WITNESS: Yes, sir.

6 THE COURT: -- part of my question  
7 before was do they prove each other, and what  
8 I meant by that is if you apply metric one to  
9 the data and you apply, let's say, metric  
10 four to the data, do you come up -- do you  
11 come up with the same conclusion, the same  
12 findings or different findings?

13 THE WITNESS: Different findings, your  
14 Honor, because they're different formulas,  
15 different algorithms.

16 THE COURT: So is it fair or unfair to  
17 suggest that a distributor or a manufacturer,  
18 right, can apply one of the -- one of them to  
19 the data and come out fine, and another one  
20 to the data and come out in trouble?

21 THE WITNESS: Well, if I understand your  
22 question, your Honor, the data, the  
23 transactional data is different for each  
24 Defendant, so that's a very specific set of  
25 purchases.

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So if you were to apply the same formula or the metric, the same formula to each of the Defendants, the numbers would be different, because the purchases and the triggers would be different.

The only common thing that would occur is the same formula would be applied to the set of transaction data for each of the different Defendants.

THE COURT: Let me get this right.

You determine the metric based upon the policies, procedures, and means and methods of the distributor or manufacturer or whatever, they tell you what the metric is?

THE WITNESS: Of four of the five. The first one was the Masters metric, which was taken right from their policies. The other four metrics were used by one or more of the Defendants that I examined as part of the litigation.

For example, the three times 12-month average, that was used by a couple of the Defendants in the litigation but not by all Defendants, but it was applied to each of the

1                   Opioid Frye Hearing/Mr. Rafalski                   144  
2                   Defendants.

3                   THE COURT:   Okay.   I have nothing  
4                   further.   You're excused, sir.

5                   THE WITNESS:   Okay.   Thank you very  
6                   much, your Honor.

7                   THE COURT:   Thank you.

8                   Okay.   Now, the next witness up is  
9                   Dr. McCann I think, right?

10                  MS. CONROY:   Dr. Craig McCann.   He's one  
11                  of the data analysts.

12                  THE COURT:   Beg your pardon?

13                  MS. CONROY:   He's one of the data  
14                  analysts.

15                  THE COURT:   Is he available today -- we  
16                  have him scheduled for tomorrow but is he --

17                  MS. CONROY:   Yes, he's not available  
18                  today.   We have him scheduled for tomorrow  
19                  morning, and he is available, obviously,  
20                  tomorrow morning.

21                  THE COURT:   All right.   Then we'll --  
22                  oh, by the way, did any of you get any  
23                  information for the Court about that Summons  
24                  with Notice that's floating around.

25                  MR. SHKOLNIK:   Your Honor, I haven't had



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a chance to get in touch with that lawyer.  
As soon as we finish reaching out to them and  
I'll report to the Court. I'll, of course,  
contact Miss Licardi, and I'll let you know  
ASAP.

THE COURT: All right. Thank you all.  
I'll see you tomorrow.

Now, there was something else we had  
discussed at the close of yesterday's  
testimony. The issue was on Thursday and  
Friday of this week. Do you recall that?

MS. CONROY: Yes, your Honor.

THE COURT: Now, I read the first waive  
of letters. The first waive of letters  
suggested that certain Defendants were  
opposed to moving, moving those two dates to  
the end.

Then I got another waive of letters that  
seems to be that everybody is on board with  
keeping Thursday and Friday open. Am I  
right? Am I wrong?

MS. CONROY: My understanding and,  
obviously, I won't speak for the Defendants,  
but I have spoken to them, that both sides

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2                   are in agreement to move Ms. Keller, who will  
3                   be a live witness, to September.

4                   THE COURT:   Okay.   What I'm waiting to  
5                   hear is, I think you're aware of the fact  
6                   that the Administrative Judge had to do a lot  
7                   of shuffling with judges in order to  
8                   accommodate us the way he has.

9                   This part is dedicated to guardianship  
10                  matters, and there are matters scheduled for  
11                  one of the dates that you're suggesting. I'm  
12                  waiting to hear from Judge Crecca. I haven't  
13                  contacted him yet today, I think my office  
14                  has to find out if they can accommodate us,  
15                  so you'll know first thing in the morning.

16                 MS. CONROY:   So whether the 11th or the  
17                 14th would potentially be a problem?

18                 THE COURT:   Yes.   The next witness is  
19                 a -- I think you asked for -- the next  
20                 witness, that would be Lacey Keller?

21                 MS. CONROY:   Right.   But we have a  
22                 witness, Dr. Lembke, on September 9th.

23                 THE COURT:   I have Dr. Lembke on for  
24                 September 8th.

25                 MS. CONROY:   Right.   And then we had a

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1 Stipulation at the last pretrial -- at the  
2 last conference because of clinical -- there  
3 were issues, and you agreed, and the parties  
4 agreed to move it one more day to begin on  
5 the 9th and then the 10th for Dr. Keyes. We  
6 moved it one day.

7  
8 THE COURT: Then you want another day;  
9 you want September 11th also?

10 MS. CONROY: Well, because we wanted to  
11 move Miss Keller from earlier in the schedule  
12 to later in the schedule, so we put her in on  
13 September 11th, but we can -- I mean, we can  
14 confer, if there are problems with the  
15 courtroom, we can confer with Defendants and  
16 move those witnesses if there are days that  
17 are not available to us.

18 THE COURT: Because if we back up into  
19 September 12th we have a headache, and in my  
20 order the Defendants suggest that they need  
21 two days with Miss Keller, and I can't have  
22 that. You know, I've created enough -- asked  
23 for enough favors to make this work as it is.

24 MS. CONROY: Your Honor, we could -- our  
25 problem was Dr. Lembke on the 8th, if that's

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an open -- if that's an open day, that's an open day for us, and I can't tell you sitting here which witness we could put on the 8th. It wouldn't, obviously, be Dr. Lembke, but one of those other witnesses could go on the 8th.

THE COURT: Okay. We'll jump on it right away.

MS. CONROY: Thank you.

THE COURT: You're welcome.

\* \* \*

C E R T I F I C A T I O N

I, Stephanie Casagrande Hague, CSR, RPR,  
an Official Court Reporter of the State of  
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